

INTERNATIONAL TRADE AND PHARMACEUTICALS

JOINT HEARING
BEFORE THE
SUBCOMMITTEE ON INTERNATIONAL TRADE
AND THE
SUBCOMMITTEE ON HEALTH CARE
OF THE
COMMITTEE ON FINANCE
UNITED STATES SENATE
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INTERNATIONAL TRADE AND PHARMACEUTICALS

TUESDAY, APRIL 27, 2004

U.S. SENATE,
SUBCOMMITTEE ON INTERNATIONAL TRADE AND THE
SUBCOMMITTEE ON HEALTH CARE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:00 a.m., in room SD-215, Dirksen Senate Office Building, Hon. Jon Kyl (chairman of the Subcommittee on Health Care) and Hon. Craig Thomas (chairman of the Subcommittee on International Trade) presiding.

Also present: Senators Lott, Snowe, Santorum, Smith, Baucus, Breaux, Graham, and Lincoln.

OPENING STATEMENT OF HON. JON KYL, A U.S. SENATOR FROM ARIZONA, CHAIRMAN, SUBCOMMITTEE ON HEALTH CARE

Senator KYL. This joint hearing of the Subcommittees on Health Care and International Trade of the Senate Committee on Finance will come to order.

I want to begin by thanking Chairman Grassley for scheduling this unique joint subcommittee hearing. We do not often have joint subcommittee hearings, but I think that the subject matter today, covering both health care and international trade, is an issue that is uniquely suited to this format.

So, I want to thank the chairman of our other Subcommittee on International Trade, Senator Thomas, for co-chairing the hearing today. We are going to be trading off our responsibilities as the day goes on.

I was very pleased that our Trade Representative, Ambassador Zoellick, raised the issue of prescription drugs, really, for the first time in trade negotiations in the recently concluded U.S.-Australia Free Trade Agreement, and that he expects to raise this issue in future negotiations.

I have long thought that the prescription drug price controls employed by foreign countries amount to an unfair trade practice because they block the access of U.S. product to foreign markets, but worse is that the price controls impose unacceptable burdens on the United States as our consumers end up paying the bulk of the cost for research and development, probably up to 60 percent more for most prescription drugs compared to the citizens and countries that use price controls.

I think the answer in the United States is not that we should adopt price controls, which is a solution that has tremendous downsides that I hope we can explore in today's hearing, but rather than we should continue to work with other countries to reduce or eliminate their price controls. The primary reason to use trade negotiations to address foreign price controls on prescription drugs is the health and well-being of the American people, and people all around the world.

Because the United States is the only major country to allow market price for pharmaceuticals and medical devices, companies are forced to finance the bulk of their research and development costs through prices charged to U.S. consumers.

They simply cannot recoup their R&D costs in countries that impose price controls, and the resulting cost shift of the R&D burden to United States consumers is unfair.

Another result, is that much of the pharmaceutical R&D has migrated from Europe, which had been the R&D leader to the United States. We actually in-source tens of thousands of research jobs in the industry from foreign-based companies.

But while jobs and the breakthrough therapies that are created are a tremendous benefit, the American consumers cannot continue to finance this medical R&D for the entire world.

As Dr. Mark McClellan, the former Commissioner of the FDA noted, "Everyone's effort to get a free ride on new drugs will grind the global development of new drugs to a halt." He said, "It is unfair to Americans who are bearing an increasing share of the burden and cannot be expected to do so indefinitely."

While Americans have begun objecting to this unfairness, the wrong solution, as I said, in my view, is to move toward price controls in this country. If Americans import price control drugs from other countries, we are, in effect, adopting the price controls of those countries. The long-term effects of such a policy could be devastating to future R&D breakthroughs.

As the Wall Street Journal editorialized just yesterday, "The politicians and lobbyists in the U.S. who have been clamoring for drug re-importation laws to lower the cost of prescription medicines could do well to look at the devastation price controls have brought to Europe's drug industry."

In fact, I believe, from a situation where about two-thirds of the new drugs were being produced in Europe, now it is probably less than a third, with the shift coming to the United States precisely because we do not have drug control prices here yet.

It takes 10 to 15 years, and costs more than \$800 million to do the research and testing to successfully bring a new medicine to patent. Only 250 of the 5,000 screened compounds enter pre-clinical testing, and only one of five drugs that enter clinical trials is approved as a new medicine. Only 3 out of 10 marketed drugs produce revenues that match or exceed average R&D costs.

If U.S. companies had to finance breakthrough drugs only with the prices that were set by governments, we could well see pharmaceutical companies scale back their R&D activities. Many companies have, for example, already reduced, or even ended, their research and production of antibiotics. We may find that other areas face similar threats as a result of price controls.

We have an opportunity to begin reversing this trend. I think we should begin by discussing the negative repercussions of price controls with our allies in the G-8 and Organization of Economic Cooperation and Development.

Our European allies have seen the flight of their drug companies' R&D activities to America. They understand the effect price controls have had on their economies and they know that price controls inevitably lead to shortages, shortages in available drugs and a reduction in the development of new, innovative pharmaceuticals.

The world has not yet felt the full impact of price controls reducing the supply of drugs because the United States is making up much of the difference for others by paying the bulk of the world's R&D expenses.

But if we were to adopt price controls, either by allowing re-importation or by adopting actual price controls, the result for future health of the world would be devastating. I look forward to hearing the testimony of our two panels today as we will be exploring how the United States can address this very serious issue.

Before I introduce the panelists, let me turn to the Ranking Member of the Trade Subcommittee, Senator Thomas.

OPENING STATEMENT OF HON. CRAIG THOMAS, A U.S. SENATOR FROM WYOMING, CHAIRMAN, SUBCOMMITTEE ON INTERNATIONAL TRADE

Senator THOMAS. Thank you all for being here. This is a topic all of us have been concerned about in many ways. So, I think it is important for us to deal with some of the issues that we will talk about today.

We have an aggressive trade strategy to open world markets to U.S. goods. To be successful, the United States needs to negotiate agreements that eliminate barriers, create transparency and level the playing field for domestic companies doing business abroad.

Whether it is an automobile manufacturer, an agricultural producer, or a soda ash processor, opening up the world for U.S. business must remain a top priority for our trade negotiators.

We will hear testimony today from two very strong panels, I believe, regarding international trade, the impact on the U.S. pharmaceutical industry, and I look forward to that.

It is no secret that we pay the highest price for name-brand prescription drugs in the world. There is also wide acknowledgement that the U.S. industry faces significant trade barriers throughout the globe that inhibit their ability to operate in a fair and open market.

Many countries have erected trade barriers through the use of government-set price controls, volume restrictions, reference pricing, and decision-making processes that are often non-transparent. In addition, lax enforcement of intellectual property rights contributes to the trade difficulties the industry encounters.

So I think that price setting is sort of, in a way, similar to a tariff that is put on the goods. It has a great impact on what happens here. To deal with these, Congress passed the Trade Act of 2002, which established a primary objective of tightening the regulatory practices that create market distortions and effectively deny U.S. companies global access.

As we know, the issue of regulatory practices relating to pharmaceuticals was one of the last items resolved in the recently completed Australian Free Trade Agreement negotiations. It is a sensitive issue for the folks in Australia, and I respect their concerns. But it is an issue that deserved to be on the table, and one that needs to be raised in future negotiations.

I will look forward to hearing more about the Australian negotiations and how the administration will address the Trade Act of 2002's objective on regulatory practices.

In addition, I welcome witness comments on how negotiations down the road will impact the drug industry and consumers around the world, including the United States. Identifying the objective is easy. Achieving the objective is the challenge.

So I thank my friend for sharing in this hearing and hope we can deal to the basic issues and not talk so much about the details, but really kind of get down to the issue of what it means and what we might do about it. Thank you.

Senator KYL. Thank you, Mr. Chairman.

Now, to John Breaux.

**OPENING STATEMENT OF HON. JOHN BREAUX, A U.S.
SENATOR FROM LOUISIANA**

Senator BREAUX. Thank you very much, Mr. Co-Chairmen. I do not know if I am giving the position of the Democratic side on this issue or not. I would suspect that there would be a little bit of a disagreement in my thoughts on this issue.

But, very briefly, it is very clear that we pay a lot more for brand-name drugs in the United States than they do in most parts of the world. The reason for that, is because most parts of the world have artificially controlled prices. They fix prices, something that this country does not allow in any area that we do commercial business in. We believe in a free market.

So it is ironic, I think, that some would say the solution to the problem of the fact that drugs cost too much in the United States is to import another country's system of fixing prices arbitrarily by government fiat, something that we would never do in this country because it would be contrary to our beliefs in a free market system and free competition.

It is clear that U.S. consumers are getting stuck with the bill for research and development by the rest of the world. Our companies have to charge higher prices in this country because they are arbitrarily, by government fiat, forced to abide by a government edict on what they can sell their products for in other countries.

When other countries do that in other areas, we file charges against them. For instance, in the area of pork from Canada, where we currently have an industry filing a petition against Canadian pork producers because they get illegal subsidies on pork. Our position has been, we are not going to let them import pork into this country freely because the Canadian government gives them illegal subsidies.

The same thing is true with wheat from Canada. The Canadian Wheat Board arbitrarily gives more generous assistance to wheat monopolistic practices in Canada. So our members of Congress say, well, do not bring wheat in from Canada because they have unfair

government practices over there that arbitrarily allow for a cheaper price.

How about timber from Canada? There are cases against Canadian timber producers because the Canadian government gives their producers of timber special deals on property that grows timber in their country.

So our people in this country say, do not just open the door for Canadian timber because of artificial practices in that country which make the price arbitrarily lower than it should be.

But when it comes to drugs, some of our same folks are saying, oh, it is all right to import their price-fixing practices. This is not so much a fight against domestic producers as it is against governments that arbitrarily fix prices.

The answer to this, and I am glad we are having this hearing, is to look at it from a trade perspective to find out exactly what practices in foreign governments have created the situation where our consumers are being forced to pay for research and development for the entire rest of the world. Solve that problem and then we can get a fair price overseas, which would lower the prices in this country to our consumers.

I thank you for having these hearings.

Senator KYL. Thanks for that excellent statement, Senator Breaux.

Senator Santorum?

**OPENING STATEMENT OF HON. RICK SANTORUM, A U.S.
SENATOR FROM PENNSYLVANIA**

Senator SANTORUM. I would like to associate myself with the remarks made by the Senator from Louisiana. I think he said it right on, and with the other two speakers, would just thank the chairmen for holding this hearing.

The concern I have, is if we do not do a better job on the international front, then the prairie populism fires that are spreading across this country to do something about controlling drug prices here could have a devastating impact on an industry that is saving lives and improving the quality of life, not just for people here in America, but for everybody around the world. It could have a devastating impact on the economy of this country. We hear a lot of talk around this table about out-sourcing.

If there is one place that we have seen in-sourcing, it is in the pharmaceutical industry. The industries in Europe and in other areas around the world are collapsing and they are coming here. Why? Because we support the industry and the other countries do not.

You do not hear people screaming and crying about French, German, and other companies moving production and moving research off their shores and onto our shores, and there is a reason for that. We are about to enter into debates—or at least many would like to, and we actually have in the past—whether it is re-importation or a whole host of other things that could kill the golden goose.

I am very hopeful that this hearing will send a very strong message to the Trade Office, that we see this as a principle failure on the part of the United States in the area of trade negotiations, not a failure of our pharmaceutical industry to do what they should be

doing, which is to research new drugs, employ people to do it, and save lives.

Thank you.

Senator KYL. Thank you, Senator Santorum.

Senator Graham, would you like to make an opening statement?

**OPENING STATEMENT OF HON. BOB GRAHAM, A U.S. SENATOR
FROM FLORIDA**

Senator GRAHAM. Thank you, Mr. Chairman.

Let me raise another concern that we can review during this hearing. I am concerned about the interpretation that is being given to what is referred to as Annex 2C pharmaceuticals within the Australian-U.S. trade agreement that has been submitted to this committee for consideration.

There is an interpretation, specifically of Paragraph 2, "Transparency," that the effect of this is going to be to make it more difficult for Federal agencies, such as the Veterans Administration, to negotiate for preferential prices for the pharmaceuticals that are purchased.

I would like to get some discussion of whether that is a legitimate concern or not. My particular interest in this, is that not only has the very successful negotiation of the VA resulted in a cost to our taxpayers and to our veterans that is about half of what the cost for pharmaceuticals would be if they purchased it through, for instance, the average wholesale cost, but it also has set a standard by which we can encourage other Federal agencies to be equally aggressive on behalf of taxpayers and beneficiaries.

We have had a great debate as to whether it was appropriate for the Prescription Drug Medicare Reform Act that we passed the end of last year to enclose a prohibition on the negotiation for the best prices for Medicare beneficiaries. I think it was a serious, serious error and I would not like to do anything in a trade agreement that seemed to reinforce that prohibition.

I also am concerned, and would state again, I am sorry that Senator Grassley is not here, because he is the particular recipient of this request.

That is, at the earliest possible moment, and certainly prior to the Memorial Day recess, that this committee should hold a hearing on the Prescription Drug and Medicare Reform Act, focusing particularly on the fact that there is such an egregious cost in comparison to what we thought the cost was going to be.

We thought this rather, what I have referred to as "Yugo" class, prescription drug benefit was going to cost \$400 billion. Now we find that the "Yugo" is going to cost about \$535 billion.

I would like to find out why there is this discrepancy and what steps are available to us, such as eliminating the prohibition on Medicare negotiating for better prices that will reign the cost of this program back to where we had originally considered it.

So, Mr. Chairman, I would like, through you, to make that request of the chairman and Senator Baucus, who has joined us, that we have a hearing on the legislation, why it is so much more expensive than we had been led to believe, and what we can do about it, and to have that hearing as soon as possible, certainly before the Memorial Day recess.

Senator KYL. Thank you, Senator Graham. I will be sure to pass it on. I am sure you will, and Senator Baucus will as well.

I would note that there are two estimates. The CBO estimate is the one that we had to work with, as you know. Then there was the later estimate by the administration. No one really knows which estimate is closer to the truth, and until the bill is implemented we will not know.

The second point I would make, is that there were efforts to try to put cost containment on the bill, efforts that Senator Baucus can perhaps address. But he felt that that was an impossible burden for the bill to carry, and as a result, it does not have legislative cost containment efforts on it.

I am going to call upon Senator Baucus next, if that is all right with Senator Smith, then close our opening statements with Senator Smith.

Senator BAUCUS. That is fine, if you want to go first.

Senator KYL. All right. Senator Smith, then we will close with Senator Baucus.

**OPENING STATEMENT OF HON. GORDON SMITH, A U.S.
SENATOR FROM OREGON**

Senator SMITH. Thank you, Mr. Chairman, for hosting today's hearing to discuss what I believe is a significant challenge facing America's consumers, the rising price of prescription drugs.

For many Americans, the cost of prescription drugs continues to place necessary life-sustaining treatments out of reach. It is no wonder, when you consider that the price of prescription drugs has increased, on average, by 16 percent per year since 1999.

We have all heard the stories, the tragic stories about seniors forced to choose between drugs and food, or rent, or other necessities. It is tragic, because behind each of these stories is a person who needs help.

The rising costs of prescription drugs impacts all of us, young working families, middle-aged empty nesters, and business owners. According to a February, 2004 Commonwealth Fund report, 23 percent, or almost 40 million non-elderly adults in America did not fill prescriptions because of associated costs.

Our businesses also bear the burden of high prescription drugs. As a businessman, I was responsible for securing health care for my employees and their families. But over the years, the average cost has increased and has become more and more difficult.

According to the Kaiser Family Foundation and the Health Research and Educational Trust, monthly premiums for employer-sponsored health insurance in 2003 increased by 13.9 percent, the third consecutive year of double-digit increases, which means the average company paid about \$6,650 to cover one of its employees with family health insurance.

Mr. Chairman, I think that is something I hope Republicans will focus on, is the burden of providing health insurance. Many companies are beginning to drop it now, or cannot provide other increases in salaries because they are being oppressed so much by these spiraling health care costs.

Unfortunately, prescription drugs are what are leading these and it is making our companies, too often, uncompetitive in the inter-

national community. But all too often, I find that many in Washington become too caught up in telling stories of hardship and pain and forget about finding the solutions that will help our constituents.

So, I commend my colleagues for holding this hearing today, which will provide a chance to discuss the reasons that America's consumers pay significantly higher prices than other industrialized nations for prescription drugs and identify solutions that will ultimately lower prices for Americans because, have no doubt, we must act.

We must change the focus of the debate to look at developing solutions that will lower prices in the United States, making these treatments more accessible. No longer can we simply sit back and accept that Americans will pay higher prices, that we will fund R&D costs for the rest of the industrialized world. The people of my State will no longer accept that premise.

Now, I know that some have argued that the United States benefits from paying higher prices. We get access to new drugs more quickly, 4 months versus the 7- to 19-month wait in the European countries. But quick access to drugs does not matter to the 25 percent of working-aged adults and the 25 percent of seniors who cannot afford their prescription medications.

I am committed to working with all of my colleagues, including Senator Judd Gregg, who chairs the Health Committee, to explore all opportunities to lower prescription drug prices. I plan to consider a variety of options, including re-importation and using trade negotiations to secure better-priced drugs.

I am certain this hearing will provide needed insight into the progress being made by USTR in negotiating the Australian trade agreement, and to identify other opportunities where the U.S. Government can work with its trading partners from industrialized nations to address the inequity of prescription drug prices.

Thank you, Mr. Chairman.

Senator KYL. Thank you, Senator Smith.

We will close, now, with Senator Baucus, then go to our witnesses.

**OPENING STATEMENT OF HON. MAX BAUCUS, A U.S. SENATOR
FROM MONTANA**

Senator BAUCUS. Thank you very much, Mr. Chairman. Thank you, Senators Kyl and Thomas, for holding this subcommittee hearing.

Subcommittees do not often hold hearings. I think that is a mistake, frankly. I think that should change. I know the Chairman is a bit constrained with his schedule, but I would urge him, and others to encourage him, frankly, to have more subcommittee hearings, because I think we can cover a lot more ground with them. I am glad, very much, that we are having this one here today.

In particular, I welcome more hearings on drug pricing policy. Clearly, it is an extremely important issue. We all know it will become even more important once the Medicare drug benefit is implemented.

Medicare beneficiaries and other consumers tell me that drug prices are rising at twice the rate of inflation. They tell me that

the government should not stand in the way when Americans want to import cheaper drugs from Canada or from Europe.

Employers, health plans, and insurers tell me that the cost of prescription drugs is one of the fastest-growing components of health care costs in the United States, and they tell me that rising health care costs are affecting the ability of U.S. companies to compete internationally. I hear that often from a lot of the CEOs.

We need to address these issues or risk the consequences to the long-term, especially to the long-term health we have in this country and to our long-term competitiveness of our economy.

U.S. pharmaceutical manufacturers tell me that other countries have imposed restrictive pricing measures on their products. They tell me that these price controls are unfair, anti-competitive, and a root cause of higher prices in the United States.

So, clearly, we have work to do. We need to learn more about the mechanisms that other countries use to determine drug prices. We also need to learn more about how prices are determined by payors here in the United States. Frankly, we should also devote more resources and attention to comparative drug effectiveness studies. The United States is clearly behind on this front.

My sense is that there is not a single best answer to high and rising drug prices. Some claim that other countries use pricing mechanisms that are too restrictive, lack transparency, and that artificially hold down prices through government strong-arming tactics. But leaving drug pricing entirely to drug manufacturers may not be the best idea, either. The market has not contained prices that provider plans and employers pay for drugs here in the United States.

And it is my understanding that some countries actually have more, not less, transparency in the way that coverage and pricing decisions are made than we do in the United States. Transparency means that there is an open, public process for determining which drugs are covered, at what price, and why.

In the end, we must find a balance between patient access and fair pricing mechanisms. The U.S. Government may have something to learn from other nations in this regard. A balanced pricing policy must take into account the ability of consumers to get the drugs they need. We must consider U.S. trade policy and the interests of U.S. companies abroad. With regard to Medicare and other public programs, we must also consider the interests of the taxpayers.

So this hearing is a good opportunity to explore these issues: what are other countries doing? What can we learn from them? What can they learn from us?

Just a few words about re-importation. I am encouraged by new efforts to address head on the safety concerns about imported pharmaceutical drugs. Safety has been the main roadblock to moving forward on re-importation.

Chairman Grassley's bill and the bipartisan bill introduced last week provide thoughtful approaches to safety concerns that seem like reasonable policy to me. I may have differences with specific provisions of the bills, but they are a good starting point to moving forward.

I would add, however, that re-importation strikes me as a short-term fix and not a long-term solution to the higher drug prices that Americans pay. I am concerned that re-importation may encourage further movement of jobs outside of the United States.

If U.S. drug companies begin selling more drugs from Canada, they may start producing more drugs in Canada and U.S. jobs may move to Canada as a result. I am concerned that American drug manufacturers may react to re-importation in ways that harm other countries, and ultimately, American consumers.

If a large share of the American drug-buying market starts buying lower-priced drugs from Canada, American manufacturers may cut back the amount of drugs that they supply to Canada. Canadians may not get the drugs that they need, and ultimately Canada may react by restricting the ability of Americans to re-import drugs from Canada.

So we need to start thinking about the long-term implications of re-importation and about potential solutions to address these problems before they even arise.

I thank you, Mr. Chairman, and I appreciate your holding this hearing.

Senator KYL. Thank you, Senator Baucus.

I would just close our comments by noting that both Senators Breaux and Baucus spent hundreds, if not thousands, of hours in the conference committee—

Senator BAUCUS. Along with you, Mr. Chairman.

Senator KYL. Right. And one of the things that we focused on constantly through that process was ways in the new Medicare bill that we could reduce prices. One comment that Senator Baucus just made reminded me.

There are several different mechanisms that we put in the new Medicare bill designed to try, each in their own way, to help bring the cost of drugs down. There is no single magic bullet that I think that we could look to as the only way to accomplish the effort.

I suspect you are as frustrated as I am that some are looking for immediate results with a bill that is just now becoming implemented, and probably suggest that we ought to give a little bit of time for it to be implemented, too, before we rush into new solutions. That is an editorial comment. You are welcome to disagree, if you would like.

Let me introduce our panel, now. We have a great panel today, a first panel, then a second panel. Senator Thomas will chair that part of the hearing.

First, is Hon. Grant Aldonas, Under Secretary of the U.S. Department of Commerce, whose responsibilities include expanding export opportunities for our businesses, enforcing trade agreements, and enforcing U.S. trade law to deter unfair trade practices. He is going to discuss the impact of price controls in other countries on U.S. prices.

The Honorable Josette Shiner, Deputy U.S. Trade Representative, Executive Office of the President. Ms. Shiner is responsible for supervising U.S. trade negotiations in a variety of places, including Australia, importantly, as well as other regional and bilateral trade issues, and in addition, supervises the Trade Office's Departments

on Economic Analysis, Labor, Environment, Trade Capacity Building, and Public Outreach.

She will discuss the efforts to eliminate price controls, the recent Australia agreement, and the United States' access to foreign markets and the effect on our economy.

Third, William K. Hubbard, Associate Commissioner for Policy and Planning of the Food and Drug Administration. Mr. Hubbard will discuss the impact of price controls on research and development, the regulatory processes of other countries as compared to the processes here in the United States, and will also mention concerns about consumer safety.

We are delighted to have all three of you here. Secretary Aldonas, you may begin.

STATEMENT OF HON. GRANT D. ALDONAS, UNDER SECRETARY FOR INTERNATIONAL TRADE, U.S. DEPARTMENT OF COMMERCE, WASHINGTON, DC

Mr. ALDONAS. Thank you, Mr. Chairmen, I guess I should say, under the circumstances. It is a pleasure to be back in front of the Finance Committee.

It is an incredibly important issue. Just by way of background, to echo some of the comments of the members, this past year I had the privilege of going across the country as a part of the President's manufacturing initiative, in 23 roundtables, talking with American manufacturers, from very large companies to very small companies, from folks who bend metal to folks who are engaged in research and development in the pharmaceutical industry.

I have to say, the comments I heard from manufacturers echoed much of what the Ranking Member was saying about the impact of price increases in the United States and the cost of health care. A lot of our manufacturers are seeing their productivity gains eroded by rising health care costs.

They were not alone in that. Obviously, rising energy costs, torts, litigation, a number of different things were eroding our competition competitiveness, but frankly they focused most on health care. That is one of the reasons why I think it is important to be looking at the issue of price controls abroad from a trade perspective.

There are tools available to us. I think my written testimony documents some of that. I would ask that that be submitted for the record, and I just want to summarize some of my thoughts here.

As a starting point, I thought it might be useful to go back to where I started with the pharmaceutical industry in the early 1980's when I was at USTR and responsible for Latin America and the Caribbean.

At the time, we were fighting for basic intellectual property protection and to remove high tariffs and a lot of other trade barriers that were really designed to foster home-grown pharmaceutical industries in places like Brazil.

The fact that we are now talking about price controls as barriers, as well as the impact on pricing in the United States, reflects that we have made a lot of progress. In the intervening 15, 20 years, we have succeeded in establishing a broad framework of intellectual property protection, which is essential for the success of our pharmaceutical companies worldwide.

We have also had a great deal of success in terms of beating down many of the ostensible barriers, the barriers at the border that are the first sort of trip wire in terms of market access that our firms face.

Congress gave us a lot of support in that, and now Congress has asked us to take the next step. As a part of trade promotion authority, the administration was asked, now, to pursue issues like price fixing and many of the other sorts of things, the exclusions from coverage, the heavy government regulatory systems that you find in a lot of other countries that limit the returns to our industry in terms of their sales.

My point in providing some of that context is just to underscore that we still do have issues in these areas where trade agreements can be relevant, so just before touching on price fixing I do want to compliment Josette and my colleagues from USTR.

For example, if you think about the proposal in the WTO that the administration has put forward which would eliminate all tariffs on manufacturing goods, that is one of the quickest ways to get where we need to go in many parts of the development world on behalf of our industry.

To the extent that, as a part of the CAFTA, we have negotiated the immediate elimination of tariffs on 83 percent of the goods that will be going to Central America, that is the kind of arrangement that can be helpful again in eliminating the initial barriers that our industry faces.

At the same time, I also want to reflect a little bit on my time in private practice, where I spent a good deal of time with pharmaceutical companies working on issues like R&D pooling.

The very fact that they were engaging in R&D pooling reflected that we had made progress. You would not be pooling R&D on an international basis in the absence of the ability to gain access to these markets.

Having said that, it also reflected something more fundamental, which is the pernicious effect of the price control systems abroad. They literally were driving industry out of Europe and into the arms of American pharmaceutical companies because pharmaceutical companies in Europe could not generate a rate of return that was necessary for them to stay in business. At the end of the day, some of the issues I faced as a lawyer were a direct result of the consolidation of a research-based pharmaceutical industry in the United States.

It is the one market where they can generate a return commensurate with the heavy investment they make in research and development, and the heavy regulatory costs that they bear in terms of gaining approvals under FDA and its equivalents abroad.

So, there is a huge cost element that our industry bears, frankly, for the world, and there is not a sufficient rate of return worldwide. Now, what happens? Under those circumstances, it is not just a question, as far as I am concerned, about the direct effect on prices. There is a much broader impact as a result of these systems.

Like in all things in life, you tax any activity, you get less of it. These price controls work as an implicit tax on the ability of firms, on a global basis, to do the research and development which will provide benefits to an aging society in OECD countries, the devel-

oped countries, as well as find new and innovative medicines which would go after the root causes of poverty in the developing world.

So, to the extent that our friends think, in the short-term, that they are limiting costs by imposing price controls, it is a short-sighted effort that limits the overall benefit that the industry could provide if it could fully gain the rate of return they have a right to expect as a result of the investment R&D.

We bear the cost, not only in terms of the direct impact on prices, but also because there is an overall global limit on the ability to bring new and innovative medicines to the market. So, in effect, taxpayers and consumers are paying twice as a result of these foreign price control systems.

Now, what do we do, under the circumstances? The way to go after this problem, there are a number of different areas. Obviously, Congress has directed us, in the context of trade promotion authority, to go after it in the context of trade negotiations, and USTR has been successful in going after these issues with Australia.

But I also want to raise one cautionary note, which is, the truth is, we are not engaged in free trade area negotiations with many of the countries that have the most pernicious price control systems.

If you look at the system in Japan, which in effect has the double damage of both knocking down the price that our guys can return, and then averaging up the price that generics charge, in effect, what they are doing is subsidizing the generic industry at the same time they are taking a rate of return away from the new and innovative part of the practice.

Well, what does that do under those circumstances? In my perspective, what it does is it actually undercuts the benefits of things that we negotiated as part of the WTO and the intellectual property framework. If you think about a 20-year patent monopoly that creates the incentive for further innovation, and what you do is set limits on prices as an economic matter, you are eroding the benefits of the things that we tried to negotiate in the context of WTO, because people cannot take full advantage of the 20-year patents.

We have to use other tools in those areas, with Japan and the OECD countries, if we are not directly at the negotiating table with them in an FTA. What we have done successfully, I think, really across the government in tandem between USTR, Commerce, as well as many of the other players, FDA included, is work in terms of our advocacy. This is where I want to stop.

The one thing that gives me hope in all this is the recognition in Japan and Europe that they have an aging society. To be able to maintain their standard of living or increase their standard of living, the one thing they must do is raise their productivity.

Thankfully, as a result of the efforts of the Congress, as well as quick action by the President, I think what we have got is very strong growth in the United States, certainly rising productivity, which has had a dramatic impact on our future and our ability to raise our standard of living. That is not true in Japan and Europe. They lag far behind.

These sorts of systems that the government manage are part and parcel of the problem. I think what they are beginning to realize

is, as they go forward, when there are fewer workers to pay for the seniors that are going to become a part of their own social safety net, eventually the system breaks down. What it really needs is more competition.

Ultimately, the best way to solve these problems is to reward innovation and then expand the generic market so it provides the price competition on substitutable drugs that sets an outward bound on prices as an economic matter.

So in one sense, it would be better to try and actually use the market in this instance to resolve many of the issues that both our European and Japanese friends face as an economic matter than relying on further price controls that have the effect of shifting the burden onto the back of U.S. taxpayers and shifting the burden forward to future generations in the United States, as well as countries abroad.

Thank you very much.

Senator KYL. Thank you very much, Secretary Aldonas.

[The prepared statement of Secretary Aldonas appears in the appendix.]

Senator KYL. Ambassador Shiner, please.

**STATEMENT OF HON. JOSETTE SHEERAN SHINER, DEPUTY
U.S. TRADE REPRESENTATIVE, WASHINGTON, DC**

Ms. SHINER. Chairman Kyl, Chairman Thomas, Senator Baucus, and members of the committee, first, I want to thank you for your leadership on this issue. It is very, very critical. As we all know, the United States is the world's leading innovative economy. We produce two-thirds of the world's innovative pharmaceuticals, and so these issues are very central and critical to our trade agenda.

First, I would like to give you a little bit of background to USTR's work on this critical area of trade, and then talk about some of the new issues that have arisen, the directives given in TPA, how we have implemented those in our negotiations with Australia, and how we are looking forward.

I think in the United States, part of why we are so successful as an innovative economy is because we recognize how important it is to have the types of regulatory regimes that foster innovation, and also we have been the world's leader in the protection of intellectual property rights, which are at the heart and soul of innovative industries.

Those two key goals have been very much at the foundation of our trade negotiating objectives with countries around the world.

I am very proud of the fact that the Office of the USTR, working with Congress throughout the 1990's and to today, has successfully led efforts to build a worldwide system of intellectual property protections that reward innovation. Today, we see that TRIPS-compliant laws are pretty much present in every major trading nation in the world.

In our FTAs, we take those intellectual properties to an even higher level, and it enables our industries to enjoy increased protections in those countries that we do the FTAs with.

Other issues that we have been deeply involved in are fighting the rising tide of counterfeiting, the theft of patents for pharmaceutical drugs, and the proliferation of dangerous and unsafe coun-

terfeit goods. These are other key parts of our agenda globally on pharmaceuticals.

We are also working globally, regionally, and bilaterally to knock down the barriers that our pharmaceutical companies face in markets throughout the world.

My testimony includes—written testimony that I ask be submitted—examples of the results that we achieved in the WTO, in NAFTA, and in various free trade agreements regarding this, and also in bilateral consultations with countries such as Korea, Japan, China, Canada, and Mexico.

Most recently, as pointed out, I, and others at USTR, worked closely with this committee in our Australia FTA, which was the first to include special provisions addressing market access for pharmaceuticals.

In this agreement, we were able to commit with Australia to several common principles that I think are very key to the kinds of goals mentioned here today by the committee.

They include: (1) the vital role that innovative pharmaceuticals play in delivering high-quality health care; (2) the importance of research and development in developing critical medicines, and of government support for R&D, including through IPR protection; (3) the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious, and accountable procedures; and, finally, (4) the need to recognize the value of innovative pharmaceuticals through procedures that appropriately value their therapeutic significance.

These principles were reflected throughout our agreement with Australia on a medicines working group, and also numerous improvements in the regulatory, transparency, and procedures in Australia's PPS system, which represents more than 90 percent of the market in Australia.

We urge Congress to act quickly when we send up the U.S.-Australia FTA, so that we can begin implementing these and get on with our Medicines Working Group.

I would like to explain a little bit of what we learned in the process of Australia. If you look at the issue of price controls, which are present in most economies regarding pharmaceuticals, they are very complex systems.

We have learned that you really have to customize your approach to each country because the approach taken is different. But there are a number of common elements that we will see country by country.

One, of course, in every country, our companies have to go through the process of getting regulatory approval for the medicines to be able to be sold in the country. But once they do that, if there is a government health care system, they also have to go through a strenuous effort to get listed on the government formulary.

Often, this is the only market available in a country. It will be 90 percent of the market, so not to be on the government formulary basically means your medicine is blocked from that economy.

After that, they have to go through a whole process of determining what they will get paid for that medicine. TPA refers to the

goal of addressing reference pricing. Often, we will see various forms of reference pricing used.

Some countries will use reference pricing in setting a price ceiling, which will be based on a basket of prices from other countries. Some countries actually determine that their price will be no higher than the lowest price paid, others use a median price, so they will compare prices from a basket of other countries.

Another form of reference pricing that we see, is they will compare the prices within a therapeutic class of pharmaceuticals, including comparing to generics within that class.

So, for example, in one country we have dealt with, there is a whole group of new drugs that address the pre-diabetes condition, and in some countries those drugs were compared to insulin, which has been on the market for many years and is generically available, and has a very low cost. So, these new, innovative drugs are priced at the same level, and, therefore, the innovation is clearly not rewarded.

Part of the problem is, many of these systems provide no fair hearing to make a case for a drug in its pricing. They do not provide appeals. They do not provide even an explanation of how they come up with the prices set.

Often, they do not allow a readjustment of the prices over the years, and in many cases we see they do not adjust the prices once set for inflation. So if a price of a drug was set in 1988, it might be the same today as was paid then. So, you get a whole system in place, and often there is no access to even understand how the decision-making process is made.

For example, in China, they review their formulary only once every 2 years. Sometimes they miss the review, and so we have a situation in China where they have listed no new drugs since 1998. So, you have a market access issue. You have an issue of populations of people being denied access to critical medicines that can improve health. Yet, again, our companies do not have a right to make the case for more frequent hearings.

So I think the study of OECD practices that we are doing with Commerce is very critical. We need to understand each country and how they are set up in order to understand how best to address these issues.

In part, what happens when we are arguing these issues abroad, is it bumps into the social good of rewarding innovation and R&D, and it also bumps into the social good of providing affordable access to medicines. Often, these national health care systems, as you know, are a very deep part of the fabric of countries and it is not politically popular, and many countries claim politically feasible, to address these issues in a bilateral dialogue.

I think part of what we have been trying to do is understand how these systems work, work with countries to understand how these systems can deny or limit access to critical medicines, and also make the case for how we all have an interest in developing R&D globally, and how we all have to contribute to understanding how to foster that so that we can keep seeing critical medicines developed.

We find this is not a case that we necessarily have to push alone. Many countries are understanding this, and many countries have

seen R&D leave their country and come here, as pointed out by members of the committee, because their climate for innovation is not adequate.

So we are finding greater awareness. We are getting some traction in making the case. We have had a number of successes. We do feel that the agreement we have with Australia can really lay the groundwork for the work we do with other countries and other FTAs, because we think the guiding principles that are in that agreement can guide us in our future FTA negotiations.

One issue we have, is finding the right and most effective forums to raise these issues. As you know, medical issues have been raised in our regulatory dialogue with Japan, for example, and in the OECD forum.

It is most effective to raise them in the environment of an FTA negotiation, but we do not have, in the near future, any FTA negotiation scheduled with major developed countries where these are really the most critical issues—countries that could afford to bear a bigger burden of research and development. So, we look forward to your guidance and wisdom on these issues, and to working with you to chart a course forward.

I would like to just recognize that Ambassador Zoellick has named an Assistant USTR to focus on pharmaceutical policies. It is Ralph Ives, who is also our Assistant USTR for the Asian Pacific. This is the team that I worked with to negotiate the Australia FTA, so we have developed some expertise. We realize that this issue requires a lot of expertise.

His deputy, Barbara Weisel, is here today. Barbara will also be part of that team that extends the knowledge that we gained in those negotiations to other countries and our discussions with them.

So, thank you very much.

Senator KYL. Thank you very much.

[The prepared statement of Ms. Shiner appears in the appendix.]

Senator KYL. Finally, Commissioner Hubbard.

STATEMENT OF WILLIAM K. HUBBARD, ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING, FOOD AND DRUG ADMINISTRATION, WASHINGTON, DC

Mr. HUBBARD. Thank you, Mr. Chairman, for inviting the Food and Drug Administration here today.

I have a written testimony, as others do, but I will just make a few brief remarks.

While FDA's responsibility does not cover drug pricing, we do have important responsibilities for providing access, assuring access, to affordable medicines.

As you know, drugs are generally a bargain compared to things like surgery and hospitalizations, and other medical interventions. So, having access for patients for drugs is very important.

Drug companies spend hundreds of millions of dollars developing new drugs each year, and FDA works very hard to make sure that those drugs get on the market fast. We are very proud of the fact that our scientists get important, new, innovative drug therapies on the market as fast, or faster, than anywhere else in the world.

But many Americans do not realize that generic versions of brand-name drugs are actually cheaper, and we also work very hard on that. That is an area where we really do have an ability to impact price, because, in fact, generic medications are often half the cost of both either brand-name or generic medications in other countries, Germany, Italy, even Canada.

So, it is very important that people recognize that over one-half of prescriptions in the country written each year are for generic medications, and that Americans can actually access cheaper drugs that way. FDA works very hard to get those generic drugs on the market just as quickly.

But despite that, many Americans cannot afford the brand-name medicines they buy, and they are angry. We all hear about the anger from members. It clearly forces them to go to other countries to look for drugs. They go to Canada and other places, and sometimes in an almost desperate search for other drugs. We are concerned about what they find when they get there.

I think the Clerk has a handout, and I will just give you an example of what real Americans are actually confronted with in this circumstance.

This was an e-mail that one of our employees received that offered Canadian generics at a very good price, and it is a very attractive offer. You get Lipitor, Viagra, and other wonderful medications at a very good discount. So, we checked to see where the server was that sent this information, and it was in Dandong, China, which borders North Korea, the location of the recent explosion in the train station the other day. So we thought, well, these are Chinese counterfeits. So, we made a purchase.

We gave a false name and credit card, and the drugs arrived a few days later. We bought Ambience, a sleep aid, Viagra, and Lipitor. They arrived a few days later in a brown manila envelope, with a return address of Miami, Florida, a postmark of Dallas, Texas, and a reorder address in the country of Belize.

So we called the reorder number and asked, where are you? They said, we are in the United States. So, we had a different person call back again and ask where they were, and they said they were in Belize. Then we called the credit card company and said, well, who did you pay for this? Who got the money? They said, it is a company in St. Kitts, which is a Caribbean island.

I think the point in this, Mr. Chairman, is there was no Canadian connection at all. They were connections in China, in the United States, and South America and the Caribbean, but not in Canada.

But the patient is told, you are going to get this. This is Pfizer's version of Lipitor sold in Canada. It is made on the same line in Ireland. It may be just as good as the Lipitor we would buy from our corner drugstore. FDA has no way of assuring that. But I can promise you, I would have a lot more confidence in this than I would in this other thing.

So, that highlights what FDA sees as the real problem here, when people, in desperation, go seek these foreign drugs. We are very concerned about the safety aspects. In fact, we are offered a position being very opposed to re-importation and to some of the ideas members of the Senate have.

As former Commissioner McClellan testified just a couple of weeks ago, our concern is based upon these safety concerns about how to do this properly. We certainly would like to work with the Senate and the House. If the policy choice is made to bring in imported drugs, we would like to work with them to make sure that it can be done safely.

With that, I will end my remarks.

[The prepared statement of Mr. Hubbard appears in the appendix.]

Senator KYL. All right. Thank you. All of those statements are excellent, and all statements will be put in the record. This was very, very enlightening. There are so many questions to ask.

Let me start, though, with two. I will ask the first of Grant Aldonas, and then the second, to Ambassador Shiner.

Because we do not have immediate bilateral negotiations with any countries coming up, or at least very soon, particularly the countries that we are primarily concerned about here, you mentioned the fact that we would have to find other tools, other contexts in which to raise these issues.

Then Ambassador Shiner pointed out, and this is a very important point that I want to reiterate, because I found the same thing with regard to Australia and New Zealand, there is an apparent willingness, if we inform ourselves and ask the right questions, to at least consider the American point of view in things like the transparency, the appeals process, in other words, the processes by which the American companies would go through to get a drug listed on the formulary, to get, ultimately, a price, to get it reviewed properly, and so on. There is a willingness to look at those procedural things.

But these countries, as with American Social Security or Medicare, have their own versions that are sacrosanct politically. The last thing in the world that they want is for us to be raising, in bilateral trade negotiations, those highly-charged political issues. Therefore, the question really to both of you, coming at it from a slightly different way, is given the fact that there are no great bilateral opportunities quickly coming along, and given the additional fact that those kinds of negotiations may highlight to the populace of the country involved political issues that make it very difficult for them to respond to our concerns, are there other contexts in which the issues can be raised?

I mentioned the G-8 meeting, meetings of the OECD countries, where you can have a group of countries sitting around at a table discussing the issue in a way that eventually results in some policy changes, but that are initiated in their country within the political context that they have to deal with in order to achieve a result that ends up with their consumers paying a fairer share of the burden than is the case today.

Mr. ALDONAS. Mr. Chairman, the first and most important thing is, oftentimes we think of trade negotiations only when we are there in the context of the WTO or in the context of an FTA, trying to produce an agreement that we would bring to the Senate at some point.

The fact of the matter is, we are engaged in negotiations every day with virtually every country around the world about the trade barriers that our companies face.

Oftentimes, the advocacy has to take the form of saying, how can we create a cooperative framework in which we can get what we want out of the process, but allow them to save face as a part of the process.

In fact, we have seen that work with Japan and medical devices. They have begun to recognize the problems inherent in their system. For years, they had a similar sort of methodology on medical devices as they do on pharmaceuticals.

By sitting down with the Japanese and talking through the issue, the openness that you described, Mr. Chairman, to consider the perspective that we bring to the table, we have actually had an impact on their pricing methodology for the benefit of our medical equipment manufacturers.

We are now engaged in regular consultation with them, sort of once every 6 months, on health care, which is pushing them on the pharmaceutical side as well.

I do want to come back to the point I made earlier, as well. There is a reason that both, I think our European friends and the Japanese are interested in that dialogue, because they recognize they have a fundamental economic problem.

We have an issue, as I was saying earlier, about the erosion of competitiveness in this country with respect to rising health care costs, but we are keeping up with it because of the dramatic rise in productivity. That is not the case in Japan and Europe.

So the fact that they recognize their own problem or are trying to grapple with the political constituencies that are invested in the current system in their own societies, that has left them open to say, can we find another vehicle.

Now, within that framework, some of what we have been doing in response to the request from Congress on the pricing study has led us to think about whether you cannot pursue something similar in the context of the OECD.

It can be a very powerful tool in terms of persuading other countries if we can get some objective analysis about the problem, and that is one of the next steps we will take, I think, when we are done with the study ourselves. Sorry for the filibuster. [Laughter.]

Senator KYL. With the yellow light left, go ahead.

Ms. SHINER. I agree with what Grant said. I think the key here is to present this as a problem where we are all trying to find win-win solutions. I think when it is presented that way, everyone has a vital interest and access to critical medicines. Everyone has a vital interest in fostering the development of critical medicines.

On that, there is global consensus. I do not think there is any one country that I have dealt with that feels they have the solution to all of these challenges that we face. So part of the question is, how do you enter this equation? Do you do it through trade, through health ministers?

I think, in part, you have to look at fostering an international dialogue on how we are sure that we are fostering research and development and how we are avoiding a race to the bottom on prices

that will ultimately hurt the very research and development that we need.

So, I think that dialogue is possible. We have talked about the OECD as being a good forum for that, because these are countries that fundamentally are wealthier and can afford to at least have the discussion about how we do this than the countries that are truly already struggling with just getting basic access to be able to afford medicine.

So, I think it is a critical dialogue. I know that no country feels they have solved the answer to it, and we are looking at all the possible ways we might be able to discuss it.

Senator KYL. Thank you.

Senator Thomas?

Senator THOMAS. Ms. Shiner, you mentioned a couple of things. You talked about obtaining market access. What good is market access if the prices are being set?

Ms. SHINER. Well, they are both flip sides of a coin, so you have to work on both issues. There are often different sets of regulations that you have to deal with. So, one phase of what we deal with is making sure that our medicines that are produced by us, the creative products of our industry, are able to be sold.

I mean, sometimes we have a basic problem of even getting them listed. Once they are listed, we then have to deal with at least getting a fair hearing for their products and adequate pricing.

So, sometimes we can have success in one avenue and we get stymied on the other, sometimes we have success in both. For example, in our recent lead-up to the JCCT with China, we brought up two factors. One, that they had not updated their formulary since 1998, and it is a problem, again, for their citizens, in addition to our innovative industries, and that they were also looking at across-the-board price cuts in all medicines, not targeted. So, we were able to bring that up and get delays and access both of those.

Senator THOMAS. Let us talk about the topic here, and that is, we are talking about price setting that has caused us then to have to pick up the costs. You are off on all these other things. What does that have to do with price setting?

Ms. SHINER. That was the issue we were discussing with China, is they were setting the price and cutting it.

Senator THOMAS. We are talking about all these other things. We really need to have some answers to the question of, what do you do about price setting in trade negotiations?

Ms. SHINER. Senator, we have raised this issue in many, many countries. We continue to. We have had a number of successes in this area. There is nothing, per se, in WTO rules or anything that the United States would even accept that prohibits price controls generically, even though we think it is bad market economics.

Senator THOMAS. I would like to talk to Mr. Aldonas. So you would be opposed to a tariff on it, right? You would work against the tariff?

Mr. ALDONAS. Right.

Senator THOMAS. What is the difference between tariffs and price setting? It basically says you cannot charge more than this, so that is about the same as a tariff. We say we cannot do anything about that, but we can without tariffs. I do not quite understand that.

Mr. ALDONAS. No. I actually think you can try and tackle both. One of the first and most important things, in direct response to your question, is one of the reasons companies continue to try and introduce the products in the market, even though they have limits on the prices, is that, A) it introduces the product and helps create demand among consumers, and hopefully demand for changes in the system so that the products are covered and they get a remunerative return.

The other thing that I think is important to focus on, is not only talking with governments about their price-setting systems, but also why the market might be a more effective response.

Lastly, I think the other thing that is important for our pharmaceutical manufacturers, even in the face of price controls, Mr. Chairman, is the fact that they are actually part of the broader supply chain, where our health care service providers represent a certain standard and our pharmaceutical companies want to make sure that they are supplying the most innovative medicines so that the folks they serve, our health care service providers, stay ahead of the competition and continue to expand their markets. So, there are a variety of reasons why they stay in the market.

What they are finding in some cases, though, is they are bailing out. Pfizer has bailed out of France because they literally cannot generate the return they need for the sale of certain products.

Senator THOMAS. I understand there is a considerable amount of major consolidation in the industry.

Mr. ALDONAS. That is true.

Senator THOMAS. Does that have any particular impact on this, do you think?

Mr. ALDONAS. I think it does, because the Europeans have become persuaded that they are the source of their own problem in terms of driving the research-based pharmaceutical industry offshore to the United States. So, I think they are coming at it, as the Europeans usually do, from the point of view of industrial policy.

But they are recognizing this is a self-imposed cost. That is one of the reasons why I think there is some reason for discussion with the Europeans about changing the underlying systems, because they realize how much they penalize themselves.

I will say, they are doing it again on chemicals, where they have a set of regulations now that are going to be driving the chemical industry of the United States. But the consolidation that you described, Mr. Chairman, is a direct reflection of the policies they adapted on price controls.

Ms. SHINER. Can I just add, briefly, one of the differences between price controls and tariffs is that price controls typically, in most of the countries we deal with, deal with both imports and domestically produced product.

So, it does not just apply to imports or just to U.S. products, but all medicines that are delivered in the system. So, it is different in the sense that, for example, many European countries have different ways of controlling prices, and it also hurts their innovative industries.

Senator THOMAS. If they have any.

Ms. SHINER. Yes. Any left.

Senator THOMAS. Yes. Thank you.

Senator KYL. Good. Thank you.

Senator BAUCUS?

Senator BAUCUS. Thank you, Mr. Chairman.

I am told, and I want you to confirm this, is it true that R&D has really not decreased in the drug industry, but that the rate of return has decreased over the last several years? If they are not the big, blockbuster, breakthrough drugs, even though R&D spending has not decreased, but in fact, increased slightly, is that true? If so, why? What is the reason?

Mr. ALDONAS. I think the overall spending has, in fact, stayed at that level. What it has not done, is increase. What we are doing right now, I think, is seeing a fundamental shift in the pharmaceutical industry, where the next really tranche of what the pharmaceutical will do is a technological leap. We are moving heavily into the direction of biotechnology as opposed to the chemistry that is involved.

Senator BAUCUS. The point is, science just has not come up with the breakthroughs. Sometimes science moves in leaps and starts. It is not a continues curve.

Mr. ALDONAS. Right.

Senator BAUCUS. So, it is true, I think, that R&D has increased, but that there have been no breakthroughs.

I have a question about what would happen to United States drug pricing if, for example, all controls, or controls, generally, were taken off of prices in Europe, in Australia, and whatnot.

I mean, the basic argument that some make is that we have to pay excessively high R&D because those other countries have price controls, and that keeps prices down and it keeps R&D down, and so forth.

Well, let us assume, for instance, that there were no, or essentially no, pricing controls in other countries. Let us assume, therefore, that the prices rose in those countries.

What effect would that have in the United States, the drug pricing? Would it necessarily follow that the United States' drug pricing would automatically fall?

Mr. ALDONAS. Not necessarily. It would depend on——

Senator BAUCUS. Why might it not fall?

Mr. ALDONAS. Markets are segmented in this industry, for a number of different reasons. Part of it, is you have companies which are trying to make sure that the quality and safety they put on the market that people associate with their brand name, as my colleague from the FDA was describing, is something that they can protect and they can continue to ensure consumers that the name "Pfizer" represents something in the marketplace. So, they are very careful about using their intellectual property to segment markets so they can provide that assurance for themselves.

They license to a particular dealer in another country so that what they are engaged in is something that is subject to their quality controls, as a practical matter. So, markets are segmented for different reasons.

But I would say, overall, if what you did was see the elimination of price controls, you would see a much greater expansion of generics worldwide, and what you would see is much stronger com-

petition in the area of substitutable products, which we have seen over the recent years in the expansion of the generic industry, which is now 50 percent of our market. It is that which will set the outside bound on prices of new and innovative medicines.

In fact, our friends in Japan and our friends in Europe would do much better if what they were doing was relying on the market to set that sort of outward bound rather than having government bureaucrats try and second-guess the market as to what drugs are substitutable.

Senator BAUCUS. My question, though, is assuming they were to let go, what effect would that have on prices in the United States? That is my question. You are saying that prices in the United States would not necessarily fall.

Mr. ALDONAS. Not necessarily, but my expectation is that they would.

Senator BAUCUS. And I am asking, why would they? I am just speaking, not argumentatively, but just for purposes of discussion here. Say Medicare is the largest purchaser of drugs in the United States. Medicare pays what the pharmaceuticals charge, essentially. If that continues, why would prices necessarily fall in the United States?

Mr. ALDONAS. Two reasons. One, again, I would expect, with the elimination of price controls, you would see stronger competition from generics, which would set an outward bound on prices. It would have the effect of putting prices down.

The other thing is, you would really have a system worldwide, not just in the United States, that rewarded the true innovators and penalized the companies that were not engaged in innovation. That is not what we have right now worldwide.

So in both respects, both price competition from generics as well as competition from new and innovative medicines, because they can secure a decent rate of return, you would see a limit on the prices that even the innovators in the market can charge.

Senator BAUCUS. A lot of this is theory. Sometimes practice collides with theory.

Mr. ALDONAS. That is true.

Senator BAUCUS. What I am getting at is, theoretically, people have a lot of information about drugs, but as a practical matter, it is so complex, they really do not know what they are buying or getting, except for what they see on television, sometimes.

So, I just do not know the degree to which the market works here, as well in a public policy sense as it does in other areas, like I say, in buying a car or buying a refrigerator, for example.

This reminds me of where trade collided with environmental policy as we try and negotiate trade agreements, and it has collided with labor rights. We gnashed our teeth and ground our way through it and we finally found some solutions. But in the beginning, people looked at them totally differently. They could not combine the two together.

Well, we have some minimum standards, say the Jordan agreement, and so forth, and Chile, for example. Maybe the OECD is the forum to look for it to try to find how they start to merge the two together.

But trade is not health. Remembering our earlier constitutional law of ours, health and safety, that is local. People, locally, want to determine, culturally, their health policy, because health is a lot more important than a car, frankly.

So, I just would like to hear you at some point—my time has run out—some sort of threads of pursuit here, avenues of curiosity here, how we might be able to get this thing here, somehow.

Mr. ALDONAS. Senator Baucus, if I could, just to pick up on your point, I agree with you that even in the United States the market does not function as well as it could. Markets are fundamentally about information. You are absolutely right about the information available to consumers.

But, really, it is the market that should drive more information in front of the consumer. If there is anything we can do to make sure that information is available for consumers so they make an informed choice, the greater likelihood that when they are in front of the CVS pharmacy out in Arlington that they will opt for the generic. But that is the sort of thing where I think we can use the tools of the market to reinforce where we want to go.

Senator BAUCUS. I appreciate that. My time has expired. I apologize to the Chairman.

Senator KYL. I think the second panel, too, might have some information on the very important question you asked.

Senator Breaux?

Senator BREAUX. Thank you very much to the panel. Let me just state, as I said in my opening comments, there is no question that the rest of the world is sticking it to U.S. consumers of pharmaceuticals because of the arbitrary fixing of prices in these other countries requiring manufacturers here to charge more for their product in our market than they are able to get back from other parts of the world in which they sell.

Some people will argue that, well, the solution to the problem for U.S. consumers is to import their system into our country and that we are going to have their price fixing system apply to our consumers. I think that is so totally contrary to everything else we do in trade. I wanted to ask you, Grant, about the concept.

There are members who would point out that we should not allow the unrestricted export of pork products from Canada to the United States because of illegal subsidies in their country, that we should not allow the unrestricted import of wheat products from Canada because the Canadian Wheat Board grants monopolies to their producers, allowing them to have a lower price, or for softwood lumber, that we should not, for instance, allow unrestricted imports of their products from Canada into this country because of the fact that, in Canada, they give industry very favorable terms on leasing Federal property, keeping the price down.

So, there are so many examples of why we say there is an answer to this problem. It is to go after these unfair practices and fixing of prices in these countries in order to create a level playing field. But are the examples I gave you not analogous to what we are talking about here? Here is a government that arbitrarily fixes prices. They say they do. They set prices. Here is the price fixing. What is the difference in the products that I pointed out as opposed to what we are talking about here?

Mr. ALDONAS. Well, you raise a good point, Senator Breaux, in the sense that you have got an endemic problem in Canada where they set the price on a whole host of things. They opt for a particular economic model, and that has an impact on wheat, certainly. In terms of lumber, the fact that the provinces set the price of timber below the market value has a dramatic impact.

From my perspective, since the Commerce Department is supposed to be the voice of manufacturing, I do have real concerns about importing the impact of the price fixing abroad, because in effect what you are doing—

Senator BREAUX. There is no question it would be good for our consumers because we would be getting cheaper lumber, we would be getting cheaper wheat, we would be getting cheaper pork products if we did that.

Mr. ALDONAS. That is true.

Senator BREAUX. Is that not true?

Mr. ALDONAS. Yes.

Senator BREAUX. So what is wrong with that?

Mr. ALDONAS. Well, the problem at the end of the day is about where you want the investment to take place, and whether you really are concerned about American industry. If what you want is a research-based industry in the United States, which in fact is a model for what we want in U.S. manufacturing, with heavy investment in innovation, the protection of their brands, safety and quality assurances to the world market that gives them an advantage in the marketplace, the sort of thing that you want to do is ensure that you have protected those values. And we have the trade laws in these other areas for precisely that reason, as a practical matter.

Senator BREAUX. All right. Here is the problem. I look at it as a trade problem. The rest of the world is sticking it to us with their trade policies in the pharmaceutical industry. Transparency is one thing. You all did a great job with Australia, saying, let us see what you are really doing. All right. We find out what they are doing. They are fixing prices. Then you are going to say, all right, do not do that.

Now, which member of Parliament in Canada, or which member of Parliament in Australia is going to be the first one to introduce a bill to increase prices of pharmaceuticals in their country?

Who is going to do that? Unless there is some huge hammer that somebody has to put over their heads, they are not going to do it. We can have all the transparency in the world and they are not going to move one inch unless there is a reason to do it that we can give them.

Now, what reasons can we give them to raise prices of drugs in their country?

Mr. ALDONAS. Well, I think what you can do, is say the ultimate goal is lowering the cost to the consumer, and there is a better way to get there. The fact of the matter is,—

Senator BREAUX. I do not know what better way. It works pretty good when you just arbitrarily fix the prices.

Mr. ALDONAS. Having a hammer always helps, to make sure you have it in your back pocket. On the other hand, I think Senator Baucus and I have seen, in the case of British Columbia, they recognize they have got a system that is so poor in its performance

in terms of selling timber, they are finally moving on the political front to eliminate the system and move toward auctions. The reason is, they had to see their own economic interest in it.

So, I think part of it is the persuasion that these countries that are the principle problems here, Japan and Europe in particular, really do have a vested interest in making sure they move in the direction of the market at this stage.

Ms. SHINER. Can I also add to that?

Senator BREAUX. Sure.

Ms. SHINER. I think we can also effectively make the case that we are not looking at more spending, but maybe smarter spending. If you look at the patterns around the world, for example, Americans use a far greater percentage of generic drugs.

Also, generics are much lower-priced here in the United States. We reward innovation, and then when it goes off patent, the price drops and there is less reward in the generic zone.

In other countries, you see often the opposite happening, that generics get a far greater share of the health care budget, and also, for example, in Europe, only 16 to 18 percent of the market is generics. In the United States, it is over 50 percent.

Senator BREAUX. They fix the prices of brand names and they increase the price of generics because a lot of the generics are being produced in their countries.

Ms. SHINER. Right.

Senator BREAUX. This is not a surprise.

Ms. SHINER. So, in part, we are not necessarily arguing for something that would change the budget, just for smarter spending that would reward innovation.

Senator BREAUX. Thank you all.

Senator KYL. One other thing I think we have discovered, is that they are beginning to realize that they are having to ration some of these drugs, and the health concerns of their own citizens might eventually rise to be a big consideration.

Senator Santorum?

Senator SANTORUM. Well, Senator BreauX asked a lot of the questions I was going to ask, and asked them better than I did. So, thank you, Senator BreauX. I appreciate those comments.

That is the problem. I hope that you are hearing it loud and clear, at least from many members up here, that we have serious concerns that we would like to see you folks act upon with respect to trade negotiations and this subject, and it is costing American consumers.

I think the point you make, I think it is also costing the consumers in other countries quality health care. I think that is our greatest pitch that we can make to the rest of the world, that they have to begin to participate.

You are seeing it in Europe, that it is costing them quality jobs, because a lot of those jobs are coming to my State. The research jobs are consolidating. They are consolidating in Pennsylvania, New Jersey, North Carolina, and places like that, and we thank you. We hope you continue.

The fact of the matter is, the concern I have, is that there are colleagues up here on this panel, and there are many colleagues who are not on this panel who want to adopt the Canadian pricing

system—it is called re-importation of drugs—or they want to adopt the Australia prices, so we can re-import from Australia.

My question to you is, if we do not solve this problem quickly and Congress does something, I would say, ill-advised in passing re-importation, what do you see as the impact on this country and our ability to come up with any kind of rational scheme of trade negotiations?

Mr. ALDONAS. Senator, I think we will see what we have seen in Europe. There will be disinvestment in the United States, a loss of employment opportunities, and, frankly, loss of an industry that is a huge multiplier in terms of what it provides, not only in terms of direct employment and sales in the United States, but some of the things that help our health care providers offer the premier health care in the world, and have created new export markets as a result.

So if that is the thing you want to destroy, which in many respects is the future of American manufacturing, that model, probably the surest way to do it is to limit the rate of return that these companies can generate, not just in the United States, but worldwide.

Ms. SHINER. One of the trade areas that this kind of bumps into is the area of what we call parallel imports, where we give, under our intellectual property rights, the owner of a patent the right to distinguish what market their product sells in.

Importation also conflicts with that very important trade principle that we have seen for our innovators to be able to keep control of the value of their products. So, that is one area that would need to be addressed as we look at that issue.

Senator SANTORUM. Senator Baucus mentioned this, and I am just curious. If we pass re-importation, I would assume, if you are a drug company and you have re-importation from “Canada”—and as we have seen from this, re-importation from Canada does not necessarily mean Canada—what would be the reaction with sending your drugs to Canada in the first place if you knew that that was going to undermine your market here in the United States?

Mr. ALDONAS. You would be less interested in sending the drugs to Canada, frankly. The thing that you just showed, and that our friend from FDA brought, is the single biggest problem that companies face. If you think what they are investing in is not just the research and development, it is the development of the brand name, Pfizer, Lipitor, those sorts of things. As long as you see that sort of thing, it is destroying value every day it is in the market.

Senator SANTORUM. I want to ask Mr. Hubbard. Senator Thomas and I were looking at some of these drugs. All these drugs have gone generic? Have their patents expired?

Mr. HUBBARD. Oh, no. No. No.

Senator SANTORUM. I did not think so.

Mr. HUBBARD. Oh, not at all.

Senator SANTORUM. So these are “generic” equivalents to drugs that really should not have any generic equivalent available.

Mr. HUBBARD. That whole document is a lie. Everything on there is a lie.

Senator SANTORUM. This is what we want to legitimize with people who want to re-import drugs from Canada. This, I assume, would be a legal thing under a re-imported drug statute.

Mr. HUBBARD. Well, depending on how it passed, it could be. Sure.

Senator SANTORUM. Can I ask, did you test these drugs to see if they were what they were supposed to be?

Mr. HUBBARD. We have not yet, but we do not really need to. This is a picture of them. They may have active ingredient in them. We have seen some of these foreign products where the counterfeiter will put a little active ingredient in, so when you do your initial test it comes out positive, so you think that it is really the drug.

Then you have got to do much more sophisticated testing to determine whether it is really therapeutically the same, and I do not think we have gotten to that level yet. But it is clearly a counterfeit drug.

Senator SANTORUM. Thank you. Go ahead.

Ms. SHINER. We have also found medicines with cement inside, and other materials that would be toxic.

Senator SANTORUM. Is it not true that maybe a small part of the reason drugs are more expensive here, is we have a much more stringent process to get drugs approved in this country and it costs more?

I mean, we are concerned about safety to the point where we drive up the cost of drugs in this country because we want to make sure that our consumers are getting a safety product.

Mr. ALDONAS. Yes. I mean, it is not only that we are concerned about safety. In fact, when a company like Pfizer goes all the way through FDA's process, what they are guaranteeing to the world, and FDA is guaranteeing to the world, is this is the best damn product on the market.

If you have things that are constantly chipping away at that, like the sorts of things that get sold on the Internet, you can imagine the loss of value in terms of the investment.

Also, the expense that they have gone through at FDA just so they can have that imprimatur at the end of the day. And while I do not think our Canadian friends would say that they do not have a system that is comparable to FDA's, I am confident that ours is the best.

Ms. SHINER. Ours is definitely the gold standard. As you travel and look at these systems, we have created the gold standard.

Senator SANTORUM. Gold standard also means most expensive, does it not?

Mr. ALDONAS. Absolutely.

Ms. SHINER. But the consumer confidence in our regulatory system—in trade negotiations you bump into this all the time, a lack of consumer confidence in those countries in the regulatory system and the fear over new products and approvals. The fact that we have that confidence here is vital.

Mr. HUBBARD. Senator, may I say, I have often said, using a car analogy, the Americans are making the Mercedes and the Hondas, and the foreign countries are making the Pintos and Vegas. So, clearly the drugs here are the best.

Mr. ALDONAS. But he is not biased.

Senator KYL. Senator Graham?

Senator GRAHAM. Well, we may be making the Hondas, and what was the other car?

Mr. HUBBARD. Mercedes.

Senator GRAHAM. Mercedes. But we are paying the Rolls Royce price for them as well.

I think, to pick up on the questions that Senator Santorum has just been asking, is part of this question of why was there such an egregious overrun in the estimated cost of the prescription drug bill?

It would be very helpful if we could have a more general hearing on what are the practical means by which we can make quality, safe, regulated prescription drugs more available to the American consumer.

Now, I happen to have some serious questions of what I learned about the capitalist system in Economics 101, was that it was driven by supply and demand. I cannot see how effective trade negotiation, which reaches the goal of, for instance, causing Australia to give up its democratic processes of making judgments as to how they will operate their health care system, is going to have any effect on prices inside the United States.

I do not come to this alone. This is a report that was issued by our International Trade Commission. This is a commission made up of Presidential appointees, Senate-confirmed individuals whose job is to look at U.S. impacts of trade policies.

It says, on page 3, "Studies reviewed in this chapter indicate that such regulations," such as the Australia regulations, "affect prices within the home country, but there is less evidence that regulations in one country directly affect prices in other countries." That would be what you would expect from an open demand-supply-driven economic system.

So, I am afraid that the amount of time that we are spending on this issue, if the question is what can we do to reduce costs for American consumers, that we are probably overly investing and ought to be looking at some of the kind of issues that Senator Santorum has just raised that really do have the potential of doing so. That is the end of my comment.

Two questions. One, there is concern that provisions in this agreement will have the effect of reducing the ability of U.S. Federal agencies, such as the Defense Department through the TriCare program, the Veterans Administration, the Medicaid and the Medicare program in affecting prices inside the United States through effective negotiation. Is that a concern that we should be concerned about?

Ms. SHINER. Senator, our agreement with Australia explicitly carves out government procurement, as in our VA and DoD systems. We work very closely with our departments to ensure that it would keep intact our entire program. So, it explicitly carves out government procurement.

Senator GRAHAM. Is that in the annex?

Ms. SHINER. Yes. It is in Annex 2. You will note there is a footnote right under there, Footnote 1 under "transparency that carves out government procurement."

Senator GRAHAM. Would, for instance, what the VA is doing, or what I think Medicare ought to be doing, come within that carve-out?

Ms. SHINER. I am sorry. What you think VA should be doing?

Senator GRAHAM. No, what it is doing. The VA is very aggressively negotiating with pharmaceutical companies and is getting better than a 50 percent, on average, discount.

Ms. SHINER. Right.

Senator GRAHAM. Would that be covered by this carve-out?

Ms. SHINER. Yes. All the VA programs are covered by this carve-out. It is all government procurement and all DoD programs, are covered by this carve-out.

I will also point out that, in this FTA negotiation, we were the side with, really, the trade concerns, because, again, we represent two-thirds of the world's innovative medicines. Those are sold heavily into Australia.

We have a letter that deals with the transparency concerns in the PBS that applies to their PBS system, which represents more than 90 percent of their market and is a vital concern to our industries.

In the Annex, I think these principles are ones that we subscribe to and we have been promoting. Then in one area of government procurement, it carves that out.

Senator GRAHAM. My time is almost out. I would like to ask a second question. That is, in the Annex, Paragraph 1(d), there is a statement about the need to "recognize the value of innovative pharmaceuticals through the operation of competitive markets or the adoption or maintaining procedures—and this is what I am particularly interested in—that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical."

The reality is, there has been active opposition, including by this administration, to the requirement that pharmaceuticals provide the same information of efficacy to the consumer as we do—for instance, I bought a bag of raisins. It has all kinds of information about the efficacy of raisins.

But if I want to go down and try to evaluate, is Lipitor or Zocor, or if there is—and I do not think there is a generic yet available—which is the most efficacious, there is almost no information made available to me, although that information is available.

Ms. SHINER. Yes.

Senator GRAHAM. Are we going to start advocating that we provide efficacy information to the consumers?

Ms. SHINER. The issue here was the right of our companies to be able to make the case. In the United States, of course, my doctor that I visit can advise to me which one he feels is of most therapeutic value. Under many government health care systems, that choice is not there.

So, the opportunity to make that case is the principle that we really felt was important, and often that is denied to either the companies, or the medical profession are denied that opportunity under certain national health care systems.

Mr. HUBBARD. Senator Graham, the Congress has instructed the Department of Health and Human Services to begin to collect that sort of data to compare effectiveness, and the Agency for Health

Care Quality Research is doing some of that, and also the Medicare program will be doing that.

Senator GRAHAM. I know we can collect the information. But when is the information going to be made available to the American consumer?

Mr. HUBBARD. Well, in fact, the goal is to compare drugs for their effectiveness, and then disseminate that information. But in all cases, that initial data comparison has not occurred, and that is what Congress has asked the Department to do.

Senator GRAHAM. When do you think it will be available?

Mr. HUBBARD. Well, the FDA is not involved in that. Our job is to approve it for safety. We do not do the comparative efficacy. So, I am not that close to it. We can certainly get back to you on the record on that.

Senator GRAHAM. Good. Thank you.

Senator KYL. Great.

Senator Smith?

Senator SMITH. Mr. Hubbard, is anyone pursuing a case against these scheisters?

Mr. HUBBARD. Yes. We have had many cases like that. Unfortunately, Senator, there are all too many of them. There are hundreds, perhaps thousands, of those individuals, selling drugs that are purported to be good, American drugs that are being purchased from a foreign country, when in many, many cases we think it is not an American drug to begin with, and could be counterfeit or otherwise a problematic drug.

Senator SMITH. Do we pursue these people with Canada or do they have a separate system?

Mr. HUBBARD. Well, Canada has no involvement in that. There is no Canada connection, except for the fact that they claimed to be in Canada.

Senator SMITH. I know from Canadian friends, selling drugs to America is a major, major league industry in Canada right now. I would think they would care about the representation of this being their country. So are they pursuing these things?

Mr. HUBBARD. We have certainly heard expressions of concern. But, just like the FDA, they cannot reach outside Canada to a business that may be in China, or the Caribbean, or Latin America.

Senator SMITH. I think your point is very well taken. I wish the American people understood a little better the amount of fraud that is out there in connection with the use of the name of Canada and pharmaceuticals, because it is much more dangerous, I think, than most people recognize.

I was with Senator Kyl in Australia in January and he and I and our other colleagues on this trip spent a great deal of time talking to the Australians about their drug policy and the need for transparency. Frankly, they were very transparent. They just told us how they price fixed. [Laughter.]

I guess my question is, good work. You got them to disclose. But we already knew it anyway. How will that impact American prices? Will it affect us at all for any good?

Ms. SHINER. Of course, we were dealing with the right of our companies to sell into Australia and that part of the equation is not

part of our trade agenda. I will only say that, since consumer awareness is growing about pricing, and ultimately if you—

One of the things we negotiate, frequently, is the cost, for example, of CDs and DVDs. Some countries, in fact, have threatened to put on price controls and just charge for the cost of the plastic, and we would know that American consumers would be angry if they were the only consumers paying for the part of the bill that paid for the production.

I think that awareness is growing. I think that if more countries did recognize innovation, then I think there would be demand here and more awareness for lower prices, including from all of you. I think that would have an impact.

Senator SMITH. Well, that demand is growing exponentially, because the more we learn about it the more we realize how set up the American people are to foot the bill for the whole world. A lot of us are getting tired of it and, frankly, are looking for the right answer as to how to affect this.

I rather suspect that trade agreements, while it is important to do this, are important to do, but I doubt they will have much impact on our ability to sell abroad or to lower American drug prices at home.

So I appreciate you continuing to work on it. Please do. But also, if you have got some ideas for how we can lower prices here that do not destroy this innovative engine that we have in R&D in this country, we are really hungry for some answers because they are fairly elusive.

Having said that, it is my own belief that most of what is going on here, is people are overstating the impact of trade agreements on prices here or our ability to sell over there.

What really drives prices, is our companies need to show a bottom-line return. That is what is ultimately driving prices up here, and we have got to somehow figure out what works, to sell the eggs without killing the goose.

Mr. ALDONAS. Senator Smith, if I could just add, I do not disagree with you about the individual trade agreement. I think it is a first step. A lot of what the transparency rules apply to is not just the pricing mechanism, but your ability to get coverage of your drug.

So, it is that basic market access hurdle, then you have better information about how you get through the process and make sure you are appropriately listed and your innovations are appropriately rewarded. So, there is some value to it. It is a very good start.

In the sense that what we are trying to do is create a broad policy environment throughout the developed world, which every other country uses these price fixing mechanisms or limits on coverage, we have got to start somewhere. This is the thin end of the wedge, as far as I am concerned. Overall, I think the system will have a significant impact.

Senator SMITH. One final question, Mr. Chairman, that I think is really important to understand.

Now, I was relieved to learn from the Australians that when they set prices, they just tell them what they are going to buy and the price they are going to buy it at.

But I do not believe they threaten them with disclosure of their patents. Are there countries that do threaten with disclosure? Is Canada one of those? Are there any countries where there is really no negotiating at all, it is just all a fraud and it is done by compulsory means?

Mr. ALDONAS. Well, just to be clear, when you say disclose a patent, one of the things that we do under the patent laws is ensure disclosure of the mechanism so people can try and improve on a prior art, but allow people to protect their rights and that initial investment. So, there is real value, in one sense, to the disclosure.

The problem I think you are focusing on might come home to roost in Japan, though. What they have the effect of doing by averaging prices between generics and the innovative medicines, is penalizing the guys who have invested in all of the R&D and they are providing a subsidy to the generics.

So, in one sense they are providing these economic rents that are due to the research and development to the guys who are not investing anything in R&D. Perversely, like a lot of protections in the marketplace, they do not actually encourage competition. They encourage sloth on the part of the generic industry in Japan, so as a consequence they do not provide competition that would actually help limit the price rises.

Senator SMITH. I would just simply suggest, that is where trade agreements can be of the greatest importance for the future, is to eliminate that kind of thing.

Ms. SHINER. If I could just point out, since the adoption of TRIPs, no country has used a compulsory license. Canada used to in the 1980's, and, in part because of our discussions with them during NAFTA, in part because of TRIPs, they have given up that practice and no longer do that.

So, we have not seen any incident of that since the introduction of TRIPs, which requires, if a country, in an emergency situation or other uses a compulsory license, if they did—and there has not been an incident of it—to provide remuneration to the industry. So, we have not seen that used.

Senator KYL. For the record, would you indicate what “TRIPs” stands for?

Ms. SHINER. Trade Related Intellectual Property Rights.

Senator KYL. Thank you.

Senator SNOWE?

Senator SNOWE. Thank you, Mr. Chairman.

I think it is interesting, how this discussion turns into, re-importation is actually a front for importing price controls. The issue is creating a competitive marketplace.

I think, on the other hand, it also is true that we ought to do everything that we can to make sure that we have an open trading relationship with those countries when it comes to pharmaceuticals, as well as opening up the marketplace.

As I understand it, even if you were to remove the price controls, it does not mean to say a government still would negotiate a set price with pharmaceuticals for their prices, similar to what the Veterans Administration does currently on behalf of their veterans, and the DoD. So, they would continue to negotiate a price, even if

they did not have price controls. Would that not be the case, if they had a single pair system?

Mr. ALDONAS. Yes, in the sense that what you would end up doing is having the foreign government buying the drugs much like the VA does.

Senator SNOWE. Yes.

Mr. ALDONAS. Would it necessarily be the case if they wanted the result of more competition in the marketplace to try and bring prices down? No. They ought to be opting for a model that is more driven by the market rather than trying to substitute their judgment for the real price that should be charged for a new and innovative medicine.

Senator SNOWE. I agree. But the whole issue is re-importation.

Ms. SHINER. May I?

Senator SNOWE. Go ahead.

Ms. SHINER. I just wanted to add on your question, not all governments that we deal with institute price controls. Some just do the reference pricing, where they set a price within a therapeutic class and there are different applications of that.

I think the key difference here, my health insurer negotiates prices. Everywhere in the market, there are negotiated prices. The problem is, when you have a monopoly buyer in countries where it is 90 percent of the market, they have such power that it is kind of a "take it or leave it" deal on the pricing. So, we see those very low. But some of them do not have an overall cap, as we see in Canada.

Senator SNOWE. And why would the previous trade agreements, like NAFTA, for example, have exempted pharmaceuticals? I am just interested. The intent, obviously, of these trade agreements, was to eliminate trade barriers. Why were pharmaceuticals exempted?

Mr. ALDONAS. Well, they were not exempt, in the sense that what we were doing was negotiating, for example, direct reductions in tariffs on access for our pharmaceuticals.

We were negotiating the elimination of limits on our service providers that go into the market that carry American pharmaceuticals with them as part of the health care they provide, limitations on investments. Our companies could go down there and actually establish themselves as a marketing and sales office.

A lot of things included in NAFTA actually are very helpful in terms of market access. Mexico also, at least as I understand it, does not have the same sorts of systems we are seeing in the case of Japan and the European countries.

But, having said that, if the issue is Canada, it is a legitimate question to say, what was the reason that this particular element was not covered?

Senator SNOWE. I think the only other industry exempted was oil. Am I correct?

Mr. ALDONAS. Log exports.

Senator SNOWE. Yes. Right.

Ms. SHINER. At the time of NAFTA with Canada, we were dealing with the compulsory licensing issue, which was the major concern. I think it is fair to say that there has not been a consensus,

in this country or abroad in the past, to use trade negotiations to try to change fundamental national health care systems.

As stated in the panel, people have seen trade as one thing, and health care being kind of sacrosanct, and a lot of these countries are very loathe to do that.

But where we do have a trade-related issue, we have pushed it very strongly. With Canada, the improvements on compulsory licensing were the most egregious part of that.

Senator SNOWE. Mr. Hubbard, in describing some of the safety-related issues in this chart, the bill that we introduced addressed many of those questions that we asked.

Mr. HUBBARD. That is correct, Senator Snowe.

Senator SNOWE. Are you familiar with the bill that we introduced, and some of the issues there?

Mr. HUBBARD. Yes, Senator Snowe.

Senator SNOWE. So in terms of your statement in this chart, we just do not want our legislation to be mischaracterized in any way regarding the safety-related issues that we addressed, because I think that that is critically important.

In fact, counterfeiting is more preponderant in this country. We have got a big problem with counterfeiting in America. So, there is no question that we ought to be addressing the counterfeiting of drugs being imported, and that is what we do.

The anti-counterfeiting technology that is used on \$20 bills, by all accounts, has been a remarkable success. So, we have a number of issues that have been incorporated in our legislation. Are you familiar with them?

Mr. HUBBARD. I am somewhat familiar with the legislation.

Senator SNOWE. You are somewhat familiar with them.

Mr. HUBBARD. Yes.

Senator SNOWE. Because I think it is important here. The FDA has had a long time in which to address this issue. In fact, you were required to do pedigrees back in 1992, I think, by Congress, so you can track the custody of medications. I mean, there are many ways in which to address this issue and many opportunities the FDA has had to address this issue. So, I think it is important.

I just wanted to dispel any mischaracterizations here in the part of re-importation when it comes to safety-related issues. We have addressed every single one of those issues in the legislation that we have introduced recently, and I think it is important to note that, Mr. Chairman, because otherwise you are going to create the wrong impression. This is one thing, but our legislation addresses this issue.

We are only talking about FDA-licensed, licensed on the Internet, licensed pharmacies on the Internet, FDA-approved manufacturing, pharmacists, facilities in Canada. Their list would be approved. The FDA will be inspecting these facilities, and so on, and so forth.

So, this sort of thing would not occur under our legislation. We provide the means to do it. I think it is important to do that, because we have taken the steps in this legislation to address the issues and the hurdles of safety certification by FDA and the Health and Human Services, and it has not happened.

So we are saying, all right, we understand. We share those same concerns. We want to make sure these sorts of things do not hap-

pen. This cannot happen under the provisions within our legislation.

I think it is important to recognize that so that we begin to take charge and be proactive rather than being an impediment and a barrier to overcoming some of these problems so that we can have some more price competition.

Hopefully, countries will change with respect to their price controls, and so on, and so forth. But in the meantime, I think American consumers deserve to be paying lower prices for their medication, should not be paying the highest prices in the world.

So one of the ways of doing it, is to take the steps we are doing, and also to open up the marketplace for more competition rather than subjecting Americans to a very rigid system of high prices.

Senator KYL. If there is any response, please do it quickly, if you would.

Mr. ALDONAS. Senator Snowe, I just wanted to put in a pitch for Customs as you think about the enforcement side, because a lot of this comes home to roost with the Customs Service, and they are terribly over-burdened right now.

Senator SNOWE. Yes. And we provide resources for that as well. Thanks.

Senator KYL. I am going to call on Senator Lincoln, now, but I am going to have to leave for a moment here. Senator Thomas is going to chair the next panel. If there is no objection, what I would like to do is suggest that at the conclusion of Senator Lincoln's question, any further questions be submitted in writing, with the record to be open through Friday for submission of those questions, as well as any other statements people have, so that we can then move on to the second panel.

Is there any objection to that process?

Senator BREAUX. I just had one question I thought he could probably answer very quickly.

Senator KYL. All right. Fine. I will let Senator Thomas deal with that. I will try to get back. I want to personally thank all of you for a very enlightening hearing.

Senator Lincoln?

Senator LINCOLN. Thank you, Mr. Chairman. Thanks to our panel for joining us today on such a very, very important issue to our Nation, to the economy, and more importantly to all the seniors out there that we hear from day in and day out with the incredible needs they have.

Just a couple of questions, and I will submit the rest of mine for the record to be answered. I know that there have been a lot of questions that have already been asked that I was interested in, and I apologize for being late, but I know some of those have already been answered.

I guess, Mr. Hubbard, one of the things I have been concerned about, and hearing about some of these trade negotiations and other things that have been going on, and the practices in other countries, are we also concerned about effectiveness of the new and innovative drugs that are out there?

Are we interested in seeing that these new and innovative drugs are really better than those that are already on the market? I know that is a part, or a component of some of these other countries in

terms of what they determine in terms of what they are going to pay, or how they are going to set their standards.

Mr. HUBBARD. Well, the standard for FDA to approve a drug, is that it be safe and effective.

Senator LINCOLN. Right.

Mr. HUBBARD. So it must be safe, and it must work. However, we do not make effectiveness comparisons when we approve a drug with other drugs. There is a growing movement toward doing that, and Senator Graham asked about that.

In fact, other parts of my parent department, Health and Human Services, are undertaking such comparative effectiveness studies to determine whether a given high-priced drug is, indeed, more effective than a given lower-priced drug, so that the doctor and patient really know what the most cost-effective treatment is.

FDA attempts not to make cost-effectiveness decisions, because that is not our charge and it could get us off into a different sort of mission than ensuring the safety and basic effectiveness of a drug.

Senator LINCOLN. Well, in light of how far we have grown in this country and FDA has grown, do you feel like it is an area that FDA could grow into?

Mr. HUBBARD. We are certainly very supportive of the need to do it. It is just that the FDA side is to try to focus on getting the drug on the market for that prime decision on safety and efficacy. But we are very supportive of what other agencies are doing to compare drugs so that the most effective treatment is identified.

Senator LINCOLN. So you do not really think that the FDA has a role to play.

Mr. HUBBARD. Well, we do in the sense that we often oversee the study data, the clinical trials that collect the information about a given drug.

Senator LINCOLN. You just do not want to interpret it.

Mr. HUBBARD. But other folks are doing that interpretation, and we believe they are in a better position to do that.

Senator LINCOLN. Well, with their evidence and their interpretation, do you think it is an effective tool in terms of dealing with how we look at the cost effectiveness of the drugs that we have?

Mr. HUBBARD. Absolutely. Former Commissioner McClellan, who is now running the Medicare and Medicaid programs, is very much making that a point of his tenure there, which is to determine for the taxpayer that is paying for these drugs what the most cost-effective treatment is. That process is, if anything, going to be more rigorous in the future.

Senator LINCOLN. Good. So you think you will be working with those efforts.

Mr. HUBBARD. Yes.

Mr. ALDONAS. Senator Lincoln, if I could just say, it is all about informing the consumer and then letting the market work. The more information that is available to the consumer about the effectiveness of the drugs, the price of the drugs, and to their care provider, the better off we are going to be.

Frankly, it is a system I would rather see our trading partners adopt because it makes more sense to have the market determining

what the outward bound of substitutability is than to have a government bureaucrat make that decision, at the end of the day.

Senator LINCOLN. I do not disagree with you. I just think that, in light of what we see in terms of information, I mean, I watch these commercials. My husband is a physician. I have to look over and say, what is this going to do for me that is going to make me feel like running out in this field of daisies? [Laughter.]

I mean, what is my problem? Information is a good thing, but let us make sure that it is productive information and something that is going to be helpful.

One of the questions I had for you all, was that we have seen there are more American drug companies that are producing overseas and that, basically by their own admission, production costs are cheaper and so they are able to do that.

Why have we not seen a difference in our drug prices? If, in fact, all of these things are true, you would think that because of that our drug prices would go down as well. If they are finding that they are moving a larger percentage of their production overseas, then we would see a decrease in our costs.

Mr. ALDONAS. I guess I would look at the problem economically in just a slightly different fashion, which is that you have a number of companies that have huge cost burdens in terms of manufacturing in the United States. It is tort litigation, energy costs, just run down the list.

Senator LINCOLN. Health care costs.

Mr. ALDONAS. And effectively what they are trying to do, is make sure they can generate a decent rate of return. There is an outward bound on how much they can price even new, innovative medicines, where at some point someone says, I will go without it rather than pay the price at the end of the day. So they try and find other ways to make sure they can still generate a rate of return and keep their product on the market. A lot of them are through cost savings.

What you are seeing in the pharmaceutical industry is no different, of course, than what we are seeing in manufacturing across the board, which is, how do you maintain a base of manufacturing in the United States while remaining cost competitive globally and generating the rate of return that your investors want to see so you can keep investing in the R&D that is going to carry you forward.

So, I think what they are engaging is a cost containment strategy of their own. Really, I think the right way to look at it economically, although this is hard to explain to my mother-in-law back in Minnesota, is that the prices would be higher in the absence of their ability to engage in those cost containment strategies, and that what they would end up, then, is having to charge more as a way of trying to generate the rate of return for their R&D.

Senator LINCOLN. But, again, that increase in cost would only be incurred by American seniors and not seniors across the globe.

Mr. ALDONAS. That is true. That is the fundamental problem.

Senator THOMAS. Could we see if we could wind up here?

Senator LINCOLN. You bet. I will just submit the rest of mine for the record. Thank you, Mr. Chairman. Thank you.

[The questions appear in the appendix.]

Senator THOMAS. Thank you very much.

Senator Breau?

Senator BREAUX. I just had one other follow-up question, and thank the Chairman.

Perhaps, Grant, you may be able to address it. If I were a pharmaceutical company and I found that I was exporting 70,000 pills to Canada, and the Canadian market only required 50,000 pills, I make a decision, I am going to sell what the market needs in Canada to Canada, but I am not going to sell them more than they need. Are there any rules or regulations that require a producer of any product to sell more to a country than they can market and sell in that country?

Mr. ALDONAS. No.

Senator BREAUX. All right. Thank you.

Senator THOMAS. All right. Thank you.

Well, thank you very much. This was an excellent panel. We will be continuing to work in this area. You may have some other questions submitted for written return in the next few days. So, thank you.

We are going to move on to our next panel now. It consists of John Calfee, resident scholar, American Enterprise Institute, and Gerard Anderson, professor, Johns Hopkins School of Hygiene and Public Health.

All right. Thank you, gentlemen. I appreciate you being here. I think it is very important that we get some observations and information from a different group, and you all more represent the private sector.

So, Mr. Calfee, if you would like to begin, sir.

**STATEMENT OF JOHN E. CALFEE, RESIDENT SCHOLAR,
AMERICAN ENTERPRISE INSTITUTE, WASHINGTON, DC**

Mr. CALFEE. Thank you, Mr. Chairman.

Senator THOMAS. By the way, your whole statement will be put in the record, so if you would like to summarize.

Mr. CALFEE. Thank you. I will summarize, briefly.

I am honored to be here. I am an economist at the American Enterprise Institute for Public Policy Research. My comments are my own.

I have supplied written testimony in which I discuss mainly five points, which I will briefly summarize, and then at the end make some specific suggestions for relatively simple things that some of the countries we have been talking about could do that I think would make things somewhat better.

My first point is very simple and familiar, which is the economically advanced nations of the world, other than the U.S., do, in fact, control drug prices and they do push those prices down below what they would normally be.

We do not know how far down they push those prices. We do know that almost certainly the prices in Canada, Australia, Germany, France, et cetera, those prices would almost certainly be lower than the prices in the U.S. if there are no controls whatsoever, because those countries have smaller per capita incomes and prices tend to track per capita incomes. But there is quite a bit of evidence that the prices in those countries are, in fact, quite a bit lower than could be accounted for by income disparities.

The second point, is that the patients in nations with price controls have faced substantial delays in the introduction and the use of innovative drugs. These delays appear to be caused primarily by the requirement that has been mentioned several times today, that when a new drug is approved, that drug also has to go through a second process of registration that focuses on dealing with prices.

A recent study of 85 chemical entities in 25 countries found that new drugs were launched far more slowly in nations that do require a separate registration or price approval process.

Third, pharmaceutical price controls do discourage the development of innovative, new drugs. This point is not a matter of contention amongst economists. As some people have mentioned today, price controls are one reason why Western Europe is no longer a dominant force in drug development as they were as recently as 15 or 20 years ago.

In 1990, European pharmaceutical firms out-spent American firms on research and development by roughly 8 billion euros to 5 billion euros, and by 2000 the situation was much reversed. U.S. firms were out-spending European firms by 24 billion euros to 17 billion euros.

In 1988, American manufacturers developed only 19 of the 50 best-selling drugs worldwide. By 1998, the situation again was very different. U.S. manufacturers were selling 33 of the top 50 drugs. By 2001, they were selling 8 of the top 10 drugs worldwide. In biotechnology, the most innovative sector, the pattern is quite striking. U.S. manufacturers now account for 14 of the top 15 biotechnology drugs in the world.

Fourth, there is reason to believe that economically advanced nations are beginning to use price controls as a tool for free riding on pharmaceutical R&D paid for by American consumers. The reason is simple: the medical benefits of innovative drugs apply pretty much to patients everywhere.

The marginal costs of manufacturing and distributing most drugs are small compared to development costs. Nations are, therefore, tempted to set prices that are sufficient to cover marginal costs, but are too low to motivate the innovative R&D that we all need and we are all waiting for.

This point, I would emphasize, has been developed at some length in the speeches of former FDA Commissioner Mark McClellan, who, as you know, is also an economist in addition to being a physician.

Fifth, as I mentioned earlier, I do believe that there are relatively simple things that the nations we are discussing today could undertake that would improve the situation to a fairly substantial degree.

I propose a brief list of those measures. One, again, something that has been mentioned several times, these nations could use more generic drugs and they could let competition force generic prices downward.

Two, these nations could permit a more efficient pharmacy retailing sector. Some nations, especially Germany, limit competition in the pharmacy retailing sector that props prices up. It provides them with scant incentives to minimize their costs. If they were to

reform this system, they would get lower retail prices and there would also be room for more reward for innovative drugs.

Three, these nations could eliminate heavy-handed disincentives for the use of innovative drugs. France, for example, has a system in which, if a drug is priced just slightly above the government-stipulated reference price, the patient has to pay the entire cost of the drug rather than paying for the difference. This is a strong disincentive to using innovative drugs. It is a strong disincentive to developing innovative drugs.

Four, these nations could permit something that is controversial everywhere, and that is direct-to-consumer advertising of prescription drugs. The evidence here, and the evidence in New Zealand, is that DTC advertising is a potent force for making consumers better informed about new treatments, and that might be useful in situations in which patients are actually waiting for new treatments to be made available on the market.

Five, these nations could provide for greater medical and patient input in setting prices, perhaps using something along the lines of an FDA advisory committee in which medical practitioners and patient groups would have a say in how prices are set and have a say in how rapidly drugs are introduced in the market.

Six, these nations could explore arrangements similar to what the pharmaceutical benefit managers use in this Nation. I think that the PBM price negotiating process might be a model for an alternative way in which these nations could deal with drug prices.

Seventh, and finally, I would suggest that wealthy nations of the world should explicitly—which they have not done yet—rule out any threats of compulsory licensing in connection with negotiating prices.

That concludes my oral remarks, Mr. Chairman.

Senator THOMAS. All right. Thank you very much.

[The prepared statement of Mr. Calfee appears in the appendix.]

Senator THOMAS. Mr. Anderson?

STATEMENT OF GERARD ANDERSON, PROFESSOR, JOHNS HOPKINS SCHOOL OF HYGIENE AND PUBLIC HEALTH, BALTIMORE, MD

Mr. ANDERSON. Thank you. Mr. Chairman, members of the Senate Finance Committee, my name is Gerard Anderson and I am a professor at Johns Hopkins University.

In my oral testimony this morning, I would like to make six points. My first point, is that other industrialized countries have invested considerable resources and capital in developing the appropriate use of pharmaceuticals and monitoring pharmaceutical prices.

Currently, however, the U.S. has no strategy for determining appropriate price or utilization for pharmaceuticals. Because we have done so little, it seems unfair to ask these other countries to change their programs.

My second point, is that our analysis shows that the U.S. pays twice as much for a market basket of 30 commonly prescribed pharmaceuticals as other countries. We are the outlier, not these other countries.

My third point, is that some other countries invest more on pharmaceutical research and development than the U.S. Recent data from the OECD shows that Sweden, Denmark, the U.K., and Belgium spend more on pharmaceutical R&D per capita than the United States does.

My fourth point is, even if these other countries paid more for pharmaceuticals, prices in the U.S. would not necessarily go down. You have talked about this today.

This hearing talks about the advisability of the U.S. Trade Representative to negotiate with these countries to raise their pharmaceutical prices in order to equalize their support for research and development across industrialized countries.

In order to implement this approach, the U.S. Trade Representative would need to have a target price level and encourage each country to pay this target price. This raises two important issues.

First, there would need to be an international standard to negotiate pharmaceutical prices. Two potential metrics that have been used in other countries are a desired level of research and development or a desired profit margin. What metric would be used to visualize the appropriate price?

Second of all, I am not sure what price level would be used through the negotiation, what would be determined by the negotiation. We are the outlier. We are paying twice as much as these other countries.

As part of a trade negotiation, would the U.S. be willing to accept a lower price for pharmaceuticals if international standards were adopted? I doubt it. In any case, my bottom line is that the trade negotiating strategy strikes me as pharmaceutical price fixing on an international scale.

Another approach is to rely on the free market. In my economics classes at Johns Hopkins, I teach about the free market and how it works best for certain goods and services. However, one situation where the free market does not work is when there is only one seller. This is known as a monopoly.

Pharmaceutical companies are given patents on brand-name drugs. There is a legitimate reason for them to receive a patent, perhaps the most important being that they foster the pharmaceutical research and development.

However, because of this patent protection and the resulting monopoly for that specific drug, it is misleading to state that the brand-name drugs in the United States are purchased in a free market environment. Monopolies just do not respond to the market forces.

Because pharmaceutical companies are given a government-granted monopoly for a certain drug, they have no reason to lower their prices in the United States, even if these prices were raised in other countries.

Generic drugs are different. There is competition for generic drugs because other manufacturers can compete on the basis of price and quality. It is not surprising, therefore, that generic drugs are often much less expensive in the U.S. than other countries.

My fifth point, is that economic theories suggest, therefore, that even if the U.S. Trade Representative were able to negotiate lower

prices in other countries, the pharmaceutical companies would still maintain their prices in the U.S. for these brand-name drugs.

My sixth, and final, point is that the U.S. should use prices in these other countries as the benchmark for the prices it pays for pharmaceuticals, especially in the Medicare program.

I would advocate, in fact, the approach that the Bush administration used in response to the anthrax scare. The Bush administration needed to purchase 100 million capsules of Cipro, and Tommy Thompson negotiated, on behalf of the government, a reduction from \$1.77 to 95 cents.

Does it matter that the U.S. pays higher prices for pharmaceuticals? A basic tenet of economics, is opportunity costs. If we pay higher prices for pharmaceuticals, we get beneficial pharmaceutical research and development. However, there are trade-offs.

For example, lower prices for pharmaceuticals would allow the Medicare program to eliminate the donut hole in the Medicare drug benefit.

My written testimony shows how 50 percent lower prices for pharmaceuticals would allow the Medicare program to spend exactly the same amount of money and eliminate the donut hole, and this 50 percent is what the other countries are paying. So, Congress has a real choice: higher pharmaceutical prices and more research and development, or the elimination of the donut hole in the Medicare program.

Thank you, Mr. Chairman and members of the committee for the opportunity to testify this morning. I would be happy to answer any questions.

[The prepared statement of Mr. Anderson appears in the appendix.]

Senator THOMAS. Thank you both very much.

Mr. Calfee, do you think trade negotiations can have some impact on the costs in the United States?

Mr. CALFEE. I think that negotiations could have some impact on improving the R&D environment. Whether that will have a direct impact on prices in the U.S., I think, is fairly questionable.

I think in the short run, that what several people have said is basically correct, that if they relax the price controls in these other nations, if they provide greater rewards to R&D, that would not have much of a short-run effect on prices within the United States.

It might have a pretty strong effect down the road because it means that new drugs would arrive more rapidly and you get more competition. In the short run, however, I am not sure we are going to get much price relief from dealing with the other nations.

Senator THOMAS. So you do not think the idea that we offset R&D by having higher prices here, but pick up a market by having lower prices somewhere else is the case.

Mr. CALFEE. No. I think what is happening, is that R&D is impeded. It is slowed down by the fact that the other nations are avoiding paying more for new drugs.

Now, when you slow down R&D you get a lot of bad things happening. Especially, you do not get some new drugs you otherwise might get, but also you get less competition in the markets. So, you would get somewhat more competition, but it takes a little while for that to develop.

Senator THOMAS. Mr. Anderson, I get the impression that you believe the price setting by other countries would be something we ought to do in the United States.

Mr. ANDERSON. It is something that we ought to consider, yes. I think that we need to know how much we pay for different drugs that are therapeutically equivalent so that we can decide and give to the consumer the information about what are therapeutically equivalent drugs. That is what Senator Lincoln and Senator Graham were asking for, and I think that we should do, yes.

Senator THOMAS. Information is quite different than setting price.

Mr. ANDERSON. It is. And I think ultimately for the Medicare program, you have to look at the trade-offs. For me, the trade-off is elimination of the entire donut hole and lower pharmaceutical prices. Personally, I would rather have no donut hole and lower pharmaceutical prices, but that is the choice that you have to make.

Senator THOMAS. All right.

Well, let me ask the two of you, just in a short sentence or two, what would you do, if you were in charge of the world, about the costs of pharmaceuticals in the United States?

Mr. CALFEE. I think that there are some things the FDA could do that might help to some extent. There are some drug approvals that take longer than they should. Manufacturer regulations, I think, have become quite inefficient. I think that would have some short-run effect on pharmaceuticals. I think that liability reform would help with pharmaceutical prices.

Beyond that, I think that what we are really counting on is the development of new drugs and this huge wave of patent expirations that we are in the middle of, and the arrival of new generic drugs.

In almost every therapeutic category you can mention, we have either had, or are about to have, major blockbuster drugs going generic. There is a generic version of a statin drug.

There are generics in some of the basic heart medication drugs, cancer drugs. Zocor is going to be going generic in a year or two. We are going to see a lot of prices going down, as well as new drug prices going up.

Senator THOMAS. Mr. Anderson?

Mr. ANDERSON. Essentially what we have done, is given these drug companies, for brand-name drugs, a monopoly. The way you handle monopolies is to try to control the prices through some type of rate setting. We have a whole variety of different rate setting systems to deal with monopolies, and I think we should explore those various options.

Senator THOMAS. Do you not think doing away with what you call a monopoly would take away the incentive to create new drugs?

Mr. ANDERSON. I think I would not want to get rid of patent protection at all. So, that is essentially what gives you the ability to create a monopoly.

Senator THOMAS. It sounds a little like you are contradicting yourself there. That is a monopoly.

Mr. ANDERSON. Essentially you have created a monopoly to develop research and development. What we are talking about is,

what is the rate of return that you should receive? It is no different than if you deal with a utility like an electrical company. They have a monopoly, so the question is, what is the rate of return on their capital that is appropriate?

Senator THOMAS. If you have government control, like utilities.

Mr. ANDERSON. And when I worked in the Reagan administration I had an opportunity to help develop the Medicare prospective payment system, and that is essentially a rate setting mechanism that we developed.

Senator THOMAS. Senator Breaux?

Senator BREAUX. Thank you very much. I thank the panel members as well. It was really interesting. The one experience that we have had in this country in fixing pharmaceutical prices is in Part B under Medicare, where we fixed the price of the reimbursement rate to oncologists for cancer drugs.

We were over-paying them by a couple of hundred million dollars every year, so the last Medicare bill had to say, look, we have tried to fix prices for cancer drugs and we have screwed it up so bad, we are going to have to eliminate it, because we were over-paying them. We were not under-paying them, we were over-paying them. It was just a great example of how a price fixing mechanism at the government level does not work.

It is interesting, I think, Mr. Calfee. I was looking at your statement. Of course, even without price fixing in lower income countries, the price of our product manufactured here is going to sell for less in that country than it does in this country.

We sell cars that are made in the United States cheaper in Canada than we sell them in the United States. Why? Not because of price controls, but because the per capita income in Canada is substantially less than it is in the United States.

Open heart surgery in Mexico is probably a lot cheaper than it is in Houston or in New Orleans, or anywhere else in this country because that is what the market is going to bear.

The problem becomes when it is also an additional fixed price because of government price controls that I think I am very concerned about.

Can you give me any concept as to why generics are so much more expensive in Europe, for instance, than they are in this country?

Mr. CALFEE. Well, most of those countries have not passed anything like the Hatch-Waxman Act here. The Hatch-Waxman Act gives a pretty smooth, open path for creating a generic drug and getting it on the market and manufacturing it. You can have several different manufacturers.

In some of the European countries, it is not that way. We do not have a law that says this is what you are allowed to do, these are the procedures you can follow, this is how you get a generic on the market. The result is that, in some cases, it is hard to enter the market.

It is intentionally made hard to enter the market by some of these countries because they want to preserve either a very small number of domestic generic firms or some of their domestic firms still have branded drugs in the market where they do not want to get generic competition.

So if those countries were to enact something like we have in the Hatch-Waxman Act and remove price controls, they would get cheap drugs very rapidly. One or two countries have moved in that direction, such as Canada and Britain, and they are getting a good generic market.

Senator BREAUX. Mr. Anderson, one of your recommendations, the fifth one, is that the United States should use prices in other countries as a benchmark price for the price we charge our consumers in this country.

Do you limit that to pharmaceuticals or would you say that the benchmark price of what we charge products in this country should be based on another country's price, even though that country may have a per capita income of 50 or 100 percent less than the United States?

I mean, we could find some lesser developed countries that the price of the product is really very, very low. Should that become the benchmark price of what we sell that product for in this country?

Mr. ANDERSON. Well, I think you have to look at it market by market. So if you are talking about hospitals or you are talking about physician service, most of the expenditures are for labor. So for a country that has very low labor costs, I would not expect the U.S. to have similar prices to those countries.

However, if we are talking a product like pharmaceuticals which is a product that you can buy, or computers, or something like that, I would expect that the United States would, in fact, pay similar prices.

Senator BREAUX. Why would we set our benchmark price on a country that has a 50 percent lower per capita income? How can we say that, because their per capita income is so much lower than the United States', that the price of that product in that country should be the benchmark for the price in the United States when their per capita income is half of what our country's is?

Mr. ANDERSON. I think we could set it up so that it is similar to countries like Canada, like the U.K., like Germany, like Luxembourg, which have similar levels of income to us. If we want to pay 20 percent more to subsidize pharmaceutical research, that is fine with me. The question is, why should we be paying 100 percent more? Our incomes are not 100 percent higher than those other countries'.

Senator BREAUX. Well, why not try to get them to allow a market price to occur within their boundaries based on what their market would charge as opposed to what the government says it should charge?

Mr. ANDERSON. Well, I think when you do not have a monopoly—you have essentially given these countries a monopoly when we have given them a patent to sell drugs for a period of time—there is no alternative. If you have a problem with low blood levels, red blood cells, the only choice that you have got is Epo. It is a single monopoly and there is one company that sells it, and that is Genentech.

So, they have a monopoly to sell that product, and they do—and any economist would tell you should—sell it at the highest price

they could possibly get it in a free market. So, the only way to negotiate with that is to have an equally powerful purchaser.

Senator BREAUX. My time is up.

Senator THOMAS. Thank you.

Senator Santorum?

Senator SANTORUM. To liken a patent to monopoly, I think, misses what Senator Thomas suggested, which is, we have patents to encourage people to develop. If you are saying that we are going to give you a patent but the patent does not mean anything, then I can guarantee you, I do not know of anybody who is going to be applying for patents any time soon to create new medicines. But you said very clearly that that is all right with you, as long as you get maximum prescription drug costs covered.

I think that is a legitimate point to make, but I think you need to make it a little bit more explicitly than you have. You are willing to sacrifice a lot of new drugs and cures in the future to have cheap drugs today. If that is your point, I accept that point.

I think it is a legitimate point to make, and I think there are probably people here on the panel that agree with you. But I think couching a lot of terms that might not be as obvious to folks who are listening is not necessarily a clear statement of your position. But I think I have stated it clearly. Is it not?

Mr. ANDERSON. Yes. I think you also could get more research and development through expansion of the NIH. The NIH is a major research and development activity.

Senator SANTORUM. That is what you were talking about. You suggested earlier that other countries spend more money on R&D than the United States, but you are suggesting that countries spend more, not drug companies in those countries. Right?

Mr. ANDERSON. Drug companies in those countries spend more money, according to the data from the OECD, per capita—not total, but per capita.

Senator SANTORUM. Oh. Per capita.

Mr. ANDERSON. So it would not be fair for Sweden to spend more than the United States given that they have got about 10 million and we have 280 million. But on a per capita basis, they spend more. They spend about \$100 per person, and we spend \$46 a person on pharmaceutical R&D.

Senator SANTORUM. Again, I am not too sure that is a relevant comparison. It all depends on whether you happen to have a large pharmaceutical plant in your country, and whether one was started there. Obviously, you have consolidations and you have plants moving to and fro.

So, to pick out one of the few countries left in Europe, as you mentioned, just a handful that actually still have some sort of pharmaceutical research, maybe a better comparison would be to see what the EU spends versus what the United States spends, and take something with a similar market instead of taking a small country that may have one large research facility that skews the whole equation. So, I am not too sure that is a fair comparison.

I will ask you that question, for the record, since I assume you do not have the answer as to what the EU spends per capita versus the United States.

Mr. ANDERSON. I do have, on specific countries.

Senator SANTORUM. I understand that. But if you could give me, for the record, what the total EU spends per capita versus the United States, that would be helpful to me.

Mr. ANDERSON. Sure.

[The information appears in the appendix.]

Senator SANTORUM. Mr. Calfee, you mentioned that compulsory licensing was still a problem. If you heard the testimony from before, they suggest that compulsory licensing is no longer a problem. Who is telling the truth here?

Mr. CALFEE. What I was referring to, is the fact that, under the TRIPs agreement, compulsory licensing is still lurking in the background for so-called medical emergencies. People in the industry tell me that they fear that if they give some of these nations an ultimatum and say, we are not going to sell at the price that you specify, we are willing to sell at a higher price but not the price you specify, that at some point some of these nations could say, if that happens, we will declare a national emergency and we will engage in compulsory licensing. It has not happened. It is not clear that they could pursue that under WTO rules, but no one knows. All I am suggesting, is that at some point these nations might say—

Senator SANTORUM. Those laws are still on the books in these countries, in other words.

Mr. CALFEE. The Canadian law is still on the books, the compulsory licensing laws. All I am suggesting is that they simply say explicitly, when we are negotiating prices, we will never resort to compulsory licensing in order to extort lower prices.

Senator SANTORUM. And they have not done that.

Mr. CALFEE. They have not done that.

Senator SANTORUM. I thought I read something around the time of the anthrax scare that Canada actually was threatening compulsory licensing with respect to Cipro.

Mr. CALFEE. I believe they did, and then they retracted that threat. But I believe they did do that.

Senator SANTORUM. So it is still a live threat.

Mr. CALFEE. Yes.

Senator SANTORUM. All right. Thank you, Mr. Chairman.

Senator THOMAS. Senator Kyl?

Senator KYL. Thank you. I appreciate both of you being here to testify.

When I went to Australia and New Zealand, one of the first things I had to dispel was that I was there as a representative of the pharmaceutical companies. I want to make it very clear, as a predicate to my question, that my concern is the health and well-being of American citizens, health care consumers, as well as people in other countries.

My motivation for being involved in this issue is to ensure that the best mechanism that we have for inventing and getting to market these new lifesaving drugs is preserved and protected as much as possible, not just for us here in the United States, but for people in other countries as well.

Of course, the means by which that research occurs is a combination of government support. We have doubled, we have more than

doubled, the NIH funding. There is not any other part of the government where we have done that much increase.

I think that is great, because I think that, other than freedom, Americans primarily are concerned about their health care. Just ask anybody who has had a sudden illness in the family. They drop everything else and they will do anything to return their family member to health. It is the most important thing to us.

That being the case, I supported the Medicare bill, which puts a whole lot of money into availability of prescription drugs, with a lot of mechanisms to try to reduce the price of those drugs as much as possible.

But I see another area where we have got a problem, and that is that the American consumer is having to carry most of the burden of the research and development of the production of these new drugs.

If that continues to happen, we will follow the lead of these other countries who have found it politically impossible to charge what the drugs really cost, so they fix the prices, number one, then they subsidize that, number two.

And you have already seen the hue and cry here in America to follow suit to do something to reduce the cost of drugs, including importation and price fixing. of course, there is no free lunch.

That is certainly the case with the development of these innovative, very expensive to develop, new products. So, somebody has to pay for it, and fixing prices makes it impossible. As you acknowledged, there is a trade-off there.

What I would suggest, is that we ought to be primarily concerned, and our number-one value here ought to be the highest quality medicine that we can possibly provide at a cost that is acceptable to people.

First of all, that assumes people should have a choice in the matter, that there just should not be a single payor government system that makes that decision for them, either as a specific matter or as a matter of pricing, and, second, that there be some choices involved, which implies competition.

Now, what I found in looking abroad was the beginnings of a rationing system. It is just beginning, but it is taking some countries far longer than the United States to get certain new drugs to market.

It is impossible for some of these countries to pay the subsidized costs of some of the brand-new, more expensive drugs. As a result, they are not making them available to their citizens.

So, I want to ask a couple of questions in regard to that. One has to do with the new report by the Bain Company, which you may be familiar with, but another has to do with the Business Week article about a year ago which pointed out that, with regard to Europe, there is this lengthy listing pricing process, as a result of which, the article concluded, "European consumers are heading towards second-class citizenship when it comes to access medicines. For example, in France, as many as 60,000 people have multiple sclerosis. An estimated 2,000 new cases are reported each year, yet less than half of the French patients diagnosed with MS are treated with life-saving medicines."

So, it is not just American consumers, but people abroad that might be suffering under the policies of their government. I would like to ask you to comment on it.

By the way, are either of you familiar with the Bain Company report? If not, I will just submit a question for the record on that.

Senator KYL. Mr. Calfee, let me start with you.

Mr. CALFEE. I have read a summary of the Bain report. In fact, I have read several summaries; I think they have marketed that report in several venues. But it does look like a very useful report.

I do not think there is any doubt that European patients are beginning to lose out on some of the new drugs, that the new drugs are arriving more slowly.

I think that in some cases the reason it takes so long to negotiate a price is not because the two sides are having trouble agreeing on things, but rather that the health authorities are dragging their feet because they want to wait as long as possible before they pay for a new therapy.

I would emphasize that when we talk about a trade-off between getting new drugs or lower prices for the drugs that we already have, we have to really beware in moving too far in the direction of lowering the prices and waiting for new drugs.

I mean, the Europeans are showing us that that wait can be quite some time. It will be a really, really long time if it turns out that the U.S. is no longer supporting new drug development.

I think that we ought to bear in mind how rapidly drugs are becoming generic, of the extraordinary promise of drug development that is now under way, and if we want to reduce prices, we ought to reduce prices for people who are relatively poor rather than for everyone, and make sure that R&D continues to flow. I think the Bain report has a lot of interesting comments to make about the trade-offs between these things.

Mr. ANDERSON. As a professor at Johns Hopkins University, research and development is our number-one product. So, I am absolutely in favor of research and development, as much as we can afford.

Senator Smith mentioned a Commonwealth Fund report, and let me highlight the results of that. It was a survey done in 2001, and it asked people in the U.K., Canada, Australia, New Zealand, and the U.S. if they could not fill a prescription due to cost in the last 12 months.

What they found, was that 26 percent of Americans said that they could not fill a prescription due to costs in the last 12 months; Australia, 19 percent; New Zealand, 15 percent; Canada, 13 percent; the U.K., 7 percent. So, yes, we spend twice as much. We get a lot more R&D. But our citizens are the ones who may be suffering. They are the ones who are having difficulty filling the prescription drugs.

Senator KYL. Yes. If we do not end up paying the cost by imposing a system of price controls on this country, they are not going to be available to anybody at any cost.

Senator THOMAS. All right. Gentlemen, thank you very much. I think this has been very interesting. One of the things that has not been mentioned is the over-utilization of drugs. We might take a look at that one of these days as well.

There may be some questions submitted to you in writing during the next few days. Thank you very much.

The committee is adjourned.

[Whereupon, at 12:35 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF GRANT D. ALDONAS

Thank you, Chairman Kyl, Chairman Thomas, and Members of the Committee, for holding this important hearing and for inviting me to testify before a joint session of the Subcommittees on Health and Trade. I welcome the opportunity to discuss trade issues pertaining to the pharmaceutical industry and how our efforts on the trade front intersect with global health care issues.

In the developed world, the pharmaceutical industry can make an enormous contribution not only to the quality of life, but also in reducing the cost of healthcare. In the developing world, new and innovative medicines can make a significant contribution to eradicating the root causes of poverty. In both cases, the demand for improved healthcare plays to one of our great strengths as a society and as an economy – applying American ingenuity to solve the problems confronting society and sharing our solutions through free and open trade.

The United States has been, and remains, the world leader in innovative medicine. Indeed, healthcare in general represents a growing export market for both U.S. goods and services. What holds true for the healthcare sector as a whole applies with particular force in the case of the U.S. pharmaceutical industry. While the industry serves the American public as its most important market, most of its potential customers live abroad. The latest trade figures reflect that trend – global pharmaceutical sales grew 9 percent in 2003 for a total of \$491.8 billion.

The key to opening foreign markets to U.S. goods and services in healthcare lies on the negotiating table. Trade negotiations on pharmaceuticals have, in the past, focused on market access in the traditional sense (i.e., lowering tariffs or eliminating quantitative restraints). More recently, they have focused on reinforcing a global system of intellectual property protection, particularly in the area of patent rights. Going forward, however, those negotiations will have to reach beyond the traditional forms of trade barriers to confront the distortions created by foreign pricing practices and the lack of transparency in foreign government health care systems.

I. Economic Context

As context for today's discussion, I want to emphasize the importance of a healthy research-based pharmaceutical industry to the U.S. economy. The U.S. pharmaceutical industry is, most importantly, a key investor and employer in manufacturing in the United States. In 2002, total U.S. pharmaceutical industry sales grew by 12 percent to reach \$219.2 billion or roughly 2 percent of gross domestic product (GDP). That same year, the industry employed 293,000 workers in the United States, up from 283,000 in 2001.

More broadly, the pharmaceutical industry has a tremendous multiplier effect as one of the key innovators in the manufacturing sector and the U.S. economy as a whole. In 2003 alone, the U.S. Patent and Trademark Office (USPTO) granted 3,803 patents for drugs to U.S. firms. Indeed, the industry represents a model of the direction toward which manufacturers in the United States are turning to succeed in an increasingly global economy. That model is one based on a heavy investment in innovation, the creation of a brand that signifies both safety and quality, and a commitment to after-sales services as a means both of meeting its customers' needs and maintaining the quality and safety associated with American pharmaceutical brands.

The industry also has the ability to help lower medical costs through the development of new and innovative medicines and improvements in their delivery. As I noted above, those innovations, particularly in the area of preventive care, will be needed to reduce costs to an aging population, not only in the United States, but elsewhere in the developed world. Such innovations will also be needed to reduce the incidence of diseases that take a huge toll on the developing world.

That said, the U.S. pharmaceutical industry's ability to provide those benefits depends on its ability to gain access to new markets and earn a remunerative rate of return on the sale of its products. By increasing access to foreign markets, American drug companies can spread the heavy cost of new research and development across a broader number of consumers, thereby reducing the cost to the individual and the cost to taxpayers, who ultimately pay for the medical assistance that is a part of our social safety net. On the other hand, where American firms are denied market access or are denied a market rate of return on their sales, they are forced to raise prices to recapture their research and development costs.

Moreover, limits on market access or price control, deny U.S. pharmaceutical firms the full benefit of their patent rights. The grant of a patent monopoly is designed to foster innovation in two ways. The first is by ensuring that the patent holder has a prescribed period – 20 years under both U.S. law and international norms – to recover the outlays that led to the invention. The second is to provide information on the patented product to the marketplace in order to encourage further innovation. By limiting market access or capping prices, foreign governments effectively undercut the value of the patent protection, limit the incentive patents provide for further innovation, and, ultimately, reduce the investment in research and development needed to improve upon the prior.

As holds true in other areas of the economy, if you tax an activity, you get less of it. The barriers to market access and caps on prices abroad impose an implicit tax on the introduction of new and innovative medicines worldwide. Perversely, such constraints not only limit the benefits that new and innovative medicines could provide, but also limit the expansion of the generic pharmaceutical industry, competition from which is the surest way to keep drug prices down across the board on all but new and innovative medicines.

The barriers our industry faces reach well beyond the conventional tariff and non-tariff measures facing U.S. exports in other sectors. For U.S. producers of patented pharmaceuticals,

concerns tend to center on foreign price and drug management regimes, which can push prices below what producers understand as fair market prices. Such regimes tend to limit the drugs that can be sold and reimbursed, and consumers tend to have only limited information about mainstream drugs and possible alternatives.

With respect to foreign drug pricing practices, our industry has raised the impact such practices have not only on their access to foreign markets, on research and development (R&D), and innovation as well. For that reason, Congress has directed the Department of Commerce to analyze a number of inter-related issues affecting the industry and consumers. That analysis will be complex, in large part because the pharmaceutical industry operates at the intersection of research, patents and innovation, drug regulation, and the health and wellbeing of individual American and citizens worldwide.

II. Industry Overview and Market Conditions

The American pharmaceutical industry is robust, diversified, and globally oriented. It exemplifies the innovation and creativity that power the U.S. economy. According to the IMS Market Prognosis International 2002-2006 Report, the domestic market for pharmaceuticals is expected to reach \$330 billion by 2006.¹ The U.S. pharmaceutical market is expected to show annual growth of nearly 12 percent, for the period 2000-2005. Generic drug makers' share of the prescription drug industry has itself grown from 19 percent to 47 percent since 1984. Economists predict that by 2005 generics will account for 57 percent of the drug market, by volume.

The United States is expected to spur worldwide growth in the pharmaceutical market, for the period 2002-2005. Global sales of prescription drugs (including both branded and generics) and over-the-counter (OTC) remedies already exceed \$300 billion annually. Domestic industry's cutting-edge practices are expected to increase American dominance of the global pharmaceutical market to 60.5 percent next year, according to IMS health reports. Innovative medicines remain a small share of health care spending in the United States, in spite of medicines' growing role in medical treatment.

The international marketplace offers great opportunities for expanded sales by U.S. drug companies. An aging population, the rising standard of living in developing nations, and intensified global R&D activity should generate a steady flow of new therapeutic products. During the next five years, the high-growth markets are expected to be in North America, the Middle East, and Asia, especially China, India, and Korea. Aging populations, increased wealth and large populations are the main drivers of expected growth in demand for pharmaceuticals.

At the same time, growth is not assured. The structure of the industry, particularly when combined with the heavy overlay of government regulation, can inhibit the full play of market forces. Patent protection provides R&D based producers with periods of exclusivity, but that is dependent on the receipt of a patent in each country and the companies' ability to effectively

¹ IMS Health is largest and most comprehensive private source of data and information on world pharmaceutical markets.

enforce its rights under that patent; pricing policy that affect both wholesale and retail pricing and the health and efficacy review that occurs in most countries also have an effect on the market and individual countries. In that environment together with significant restrictions on trade outside normal distributions channels, prices in one market can be relatively independent of prices in another market. Indeed, that would likely hold true even in the absence of restrictions at the border.

Government intervention varies by country, but it exists everywhere in one form or another. Governments employ a number of mechanisms and procedures to control prices, the most important of which include – comparisons with prices in other countries, reference prices to drugs with similar therapeutic characteristics, negotiated prices, and ceilings on expenditures. In addition, information on both drug choices and drug alternatives can be limited, which prevents consumers from making an informed choice.

Most industrialized countries, with the exception of the United States, have imposed a variety of regulations at the national level that deal with prices and availability. A good example is France. The French government administers the National Health System, which covers virtually every Frenchman. It is supported by the national Social Security Program, which is itself funded by contributions from employers and employees. Social Security contributions cover approximately three quarters of health expenditures. Supplemental private insurance helps patients pay incurred costs not covered by the government system.

The French government closely monitors and controls prices for drugs that are eligible for national reimbursement, making drugs relatively cheap in France, by EU standards. The current price control system was established in 1994, via a framework agreement between government and industry. The government negotiates prices with drug companies using a number of factors to determine what they will pay. The negotiated prices are based on an expected level of sales. Should sales exceed these limits, the government can require that prices be adjusted downward.

Pharmaceutical companies may set prices as they wish for name brand and generic drugs, which are not officially reimbursable, but they must limit promotional activities. Lack of reimbursement, of course, greatly limits sales. Reimbursable drugs account for approximately 83 percent of sales.² They have also imposed various other restrictions to limit the variety of drugs available in markets as well information about new drugs.

By contrast, in the United States, we rely more heavily on the interplay of market forces to determine drug prices, rather than imposing price controls or enforcing cost-containment programs. At the national level, for example, the United States has promoted the use of generic drugs, which necessarily puts downward pressure on prices, to set an economic boundary on the price of most medicines. In relying on direct governmental controls, most other industrial countries forego the benefits of competition that generics create and prices are higher in the absence of effective competition from the generic sector of the market.

² EFPIA, "The Pharmaceutical Industry in Figures." EFPIA is essentially Europe's pharmaceutical association, the equivalent of PhRMA in the United States.

Insurance companies, health maintenance organizations (HMOs) and other market participants attempt to use their market power to negotiate lower prices. They also try, to varying degrees, to limit choices or curtail use of more expensive drugs. As a result, even in the United States, the market is not pure in a technical economic sense.

There are federal and state government sponsored buying programs that involve reimbursement limits, rebates, discounts, price caps, and limits on price increases. Such programs reportedly account for only about 13 percent of sales. Public sector plans include Medicaid and programs administered by the Departments of Defense and Veterans Affairs.³

Yet, even with our departures from a perfect free market, the United States market is far different from a system such as that administered by the French and other Organization for Economic Cooperation and Development (OECD) governments. In terms of market conditions, many studies indicate that prices for prescription drug products in the United States tend to be higher than in other OECD countries. That said, the magnitude of the gap is often difficult to measure. The most significant variation is the different consumption patterns among countries, which complicates any assessment of a market basket of drugs. Other factors that make cross-border comparisons particularly complex include variations in dosages, concentrations, dosage strengths, units of measurement, and types of treatments and therapies.

Actions by the United States and other members of the OECD have resulted in a variety of government policies with regard to health care overall, and drug pricing in particular. The segmentation of the global drug market promotes wide variations in drug prices, accessibility, and prescription rates. Studies also indicate that in markets with lower prices – and lower company revenues – research, development, and drug innovation suffer.

Nations approach overall health care differently, and likewise with drug pricing policies.⁴ For example, in 2000, the United States' health care spending was 13.6 percent of total GDP. In Japan, the figure was 7.4 percent; in Canada, 9.3 percent; and in France, it was 9.6 percent. The United States simultaneously has comparatively low medicinal expenditures, as a percentage of total health care costs – only 7.3 percent, compared to 10.8 percent in Canada, 13.9 percent in France, and 15.3 percent in Japan. However, the per capita expenditure on prescription pharmaceuticals was \$293 in the United States, \$203 in Canada, \$321 in France, and \$378 in Japan. Some of the discrepancy is due to the substantially smaller population over the age of 65, 12.5 percent of Americans versus 15.7 percent of the French. Also, new drugs enter some markets more quickly than others, and such drugs tend to be more costly than existing alternatives.

³ PhRMA 2000

⁴ All of the data in the following paragraph are drawn from OECD 2000.

III. Addressing Industry Concerns Through Trade Negotiations

Rules governing the healthcare sector abroad can have a significant effect on export opportunities for U.S. pharmaceutical and other healthcare suppliers. We work closely with our industry in tackling pharmaceutical trade problems that arise within the existing framework of the WTO in cases against India, Argentina and Brazil, among others, and under other trade agreements whenever possible. That said, the current architecture of the international trading system does not address a number of our industry's concerns.

For that reason, Congress directed U.S. negotiators, in the Trade Act of 2002, to seek "the elimination of government measures such as price controls and reference pricing which deny full market access for United States products" in markets abroad. The over-arching objective is to ensure that foreign governments do not use government regulation to provide a competitive advantage to their domestic producers.

A. Basic Objectives

In pursuing the objective set out by Congress, the Administration has focused on the following six core elements.

1. Eliminating Tariffs and Non-Tariff Barriers

The first and most obvious way in which trade negotiations can create export opportunities for U.S. pharmaceutical firms is by removing the direct obstacles to market access, such as tariffs and non-tariff barriers in the form of any outright restraints on importation abroad. Removing foreign tariffs on U.S. drugs, for example, can significantly improve the availability of a wider range of healthcare options for consumers in the foreign market by eliminating what is the most regressive form of taxation on healthcare for consumers. Removing those tariff barriers also has the effect of stimulating stronger competition for local suppliers, which often provides a further spur to innovation and can lead to new entrants in the generic market which helps set an outward bound on pricing in many instances.

2. Opening Markets for U.S. Investment and Healthcare Service Providers

Market access negotiations can help expand the market for U.S. pharmaceutical products in other ways as well. For example, improving access for U.S. investment and the establishment of U.S. healthcare service providers can ensure that foreign markets are aware of and have access to the latest in healthcare options. Those advances in medicine commonly include new and innovative pharmaceuticals produced by U.S. firms. In addition, expanding the availability of supplemental health insurance that reimburses for non-regulated drugs can help in financing the cost and improving the availability of American medicines. Similarly, opening the market for new advertising and marketing services can expand the market for U.S. pharmaceuticals by informing the public of the benefits of innovation and promoting the awareness of new

medicines among consumers. Non-discrimination in these areas can increase public demand for choice.

3. Improving Intellectual Property Protection

One of the central aspects of market access in the pharmaceutical industry is the extent of intellectual property protection available in the potential market. The lack of sound intellectual property protection can interpose as significant a barrier to U.S. drugs, particularly new and innovative medicines, as any tariff or non-tariff measure. The first step is, of course, ensuring that our trading partners are abiding by their obligations under the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPs). There are, however, a number of steps beyond that baseline that are important and relevant to the pharmaceutical industry as the recent negotiations with our Central American trading partners reflect. The objective is to ensure that our trading partners are implementing state-of-the-art intellectual property protections, even where those protections are "TRIPs plus."

4. Transparency

Ensuring transparency represents a fundamental tenet of American agreements, from government procurement to standards-making processes to other regulatory practices. Rules on transparency generally require governments to ensure that rules-setting process is open and accessible to all interested parties and guard against discriminatory practices. In the case of pharmaceuticals, government systems that define which products are eligible for coverage and those that fix prices are all too often non-transparent. Trade negotiations can help open up the decision-making process in these areas, with positive benefits for further system-wide improvement. Industry's ability to inform decision makers about research and development costs, and the benefits of continuous pharmaceutical innovation, can help elected officials and the public to reach better decisions. Increasing transparency requires public officials to be more responsive to citizens' needs rather than selectively issuing reimbursement applications to hold drug budgets down.

5. Promoting Competition

By adopting rules that encourage competition in both the private and public sectors for healthcare, trade agreements can help expand the market for our pharmaceutical industry abroad. By ensuring non-discriminatory, science-based determinations in the development of product standards and in the course of approvals of products by the foreign equivalent of the U.S. Food and Drug Administration, such agreements can ensure that foreign markets are not artificially closed to U.S. drugs in ways that limit healthcare options for consumers at the expense of U.S. firms and for the benefit of their local competition. Trade agreements can also shape the market for government procurement of pharmaceuticals by eliminating "buy national" requirements that afford a preference for locally produced drugs, even when U.S. firms' products might offer a new and innovative treatment not offered by their local competition.

6. Establishing Cooperative Working Groups

Trade agreements can also establish a cooperative forum for addressing systemic problems, expanding on market access not already covered by the agreement as it goes into effect, and ameliorating specific market access problems as they arise. The goal is to help both sides gain insight and develop mutually beneficial solutions that avoid trade disputes, rather than allowing what may be a technical disagreement fester into a more intractable trade problem.

B. Recent Trade Agreements and Upcoming Negotiations

Best understood, market access negotiations and the trade agreements that follow can become proving grounds, allowing trust to build as foreign markets transform and become more open and competitive. What follows is a summary of recent negotiations with Australia and our Central American trading partners as they affect U.S. pharmaceutical interests. The summary also highlights the sorts of issues that will become the focus of upcoming talks with Thailand.

1. Australia

The recently concluded free trade agreement with Australia represents a first step toward that goal. It represents an important breakthrough that should lead, in the first instance to more transparent pricing procedures in Australia. Australia represents a \$5.4 billion pharmaceutical market; about 60 percent of the drugs sold are imported.⁵ U.S. pharmaceutical exports to Australia totaled \$539 million in 2003, a 19 percent increase over 2002. U.S. companies have invested substantially in this sector, which is highly restricted by the government's management of the national health care system.

In the case of Australia, U.S. industry has long complained that the system for being listed and priced by Australia's Pharmaceutical Benefits Scheme (PBS), the agency that reimburses pharmaceutical manufacturers for drugs prescribed by health care providers, fails to reward innovation, lacks transparency, and is plagued by delays. According to the Australian governments own study, Australia's prices for innovative drugs are among the lowest in the OECD.⁶

The recently concluded FTA contained commitments on pharmaceuticals of two sorts. First, the United States and Australia agreed to common principles for facilitating high quality health care and continued improvements in public health. Agreement on these principles will provide a common basis for future discussions on pharmaceutical issues. The two sides affirmed

⁵Domestic demand defined as turnover plus imports less exports, "Industry Sector Analysis for Pharmaceutical Industry," Dept. of Commerce, U.S. Commercial Service, Sept. 29, 2003.

⁶"International Pharmaceutical Price Differences," Australia Productivity Commission, July 2001

a shared commitment to a number of principles, including the important role played by innovative pharmaceuticals and the need to promote pharmaceutical research and development.

Second, the two sides subsequently agreed to establish a Medicines Working Group, which will foster discussion about emerging health policy issues. They also agreed to have the U.S. Food and Drug Administration and its sister agency, the Australia Therapeutic Goods Administration, work together to make innovative medical products quickly available. Australia also committed to specific steps to increase transparency and accountability of the PBS procedures. The Australian government, for example, agreed to an independent review of listing decisions, obligations to explain proposed decisions, allowing applicants to comment and memorialize reasons for decisions. Furthermore, they agreed to give meaning to these provisions by opening them to independent review.

While some worried that the U.S. might pressure the Australian government to raise domestic pharmaceutical prices, that did not happen. Under the PBS, Australians pay a small co-payment for prescriptions, and the government subsidizes the remainder. The FTA will not alter the prescriptions-framework for Australians or Americans.

2. CAFTA

The focus of our efforts on behalf of the American pharmaceutical industry in trade negotiations will necessarily vary with the agreement. In that sense, the Central American Free Trade Agreement (CAFTA) offers a contrasting example to that of Australia. The five countries involved in the negotiations represent different levels of development than Australia and the market access issues of importance to the U.S. pharmaceutical industry differ accordingly.

In strict market access terms, CAFTA reflects the importance of trade agreements in eliminating many of the traditional barriers to trade that inhibit our firms' entry into the healthcare sector in Central America. Under CAFTA, 83 percent of U.S. pharmaceutical exports will become duty-free immediately upon implementation of the agreement; tariffs on the remaining 17 percent of pharmaceutical exports will be eliminated over five years.

In addition, intellectual property protection represented a higher level of concern in Central America than in the Australian market. In the event, the five Central American countries proved willing to adopt state-of-the-art intellectual property protections that reach beyond the minimum standard required under the TRIPS agreement. The CAFTA will strengthen patent protection by (1) specifying that test data and trade secrets submitted to a government for the purpose of product approval will be protected against unfair commercial use for a period of 5 years for pharmaceuticals (and 10 years for agricultural chemicals), which sealed potential loopholes in these provisions; (2) extending patent terms to compensate for delays in granting the original patent, consistent with U.S. practice; (3) limiting the grounds for revoking a patent, thus preventing arbitrary revocation; and (4) requiring a system that prevents marketing pharmaceutical products that violate patents.

The willingness of the five Central American countries to broaden the existing

protections under their law represents a significant breakthrough. In effect, the five countries agree to adopt standards better than TRIPS-level protections, which, when fully implemented, should significantly improve the level of intellectual property protection for U.S. pharmaceutical products in Central America. The later inclusion of the Dominican Republic within that structure and subject to the same commitments will simply expand the reach of those protections.

3. Thailand

The upcoming FTA negotiations with Thailand provide an opportunity to address market access issues in the pharmaceutical area again. As required by TRIPS, the existing Thai Trade Secret Act includes a provision barring unfair commercial use of proprietary data. However, regulations for implementation are still pending, and American industry remains concerned that those regulations will not provide sufficient protection. The proposed regulations have been discussed with Thai officials under the Trade and Investment Framework Agreement (TIFA), and if needed, can also be addressed during FTA talks in late June. U.S. officials have already broached the topics of counterfeit pharmaceuticals and patent examinations, which can suffer delays of up to five years under the current Thai system. Our negotiations offer the chance to resolve these issues for the benefit of both the U.S. pharmaceutical industry and the consumer of healthcare in Thailand.

IV. Advocacy to Address Specific Impediments

In addition to trade agreements, our bilateral commissions, working groups and bilateral contacts facilitate problem solving and the elimination of specific impediments to trade in U.S. pharmaceutical products and other healthcare goods and services. Through these with straightforward aggressive advocacy and dialogue, Commerce has the opportunity to make the case that certain government policies inhibit long-term innovation and cost saving measures. In many instances, these help reduce or eliminate market access barriers for our pharmaceutical and medical device industries.

What follows is a series of examples in significant foreign markets where aggressive advocacy on our industry's behalf is contributing to the elimination of barriers to trade in U.S. pharmaceutical products or healthcare goods and services in general. The lesson to draw from these examples is that focusing on the underlying needs of our industry and the obstacles they face, while remaining flexible as to the best approach to achieve our aims, can contribute to a successful outcome in many instances.

A. China: Poor Enforcement of IPR/US-China Healthcare Forum

Innovative U.S. medicines currently account for about [25] percent of China's pharmaceutical market, which is estimated at approximately \$6 billion per year. Despite China's potential, intellectual property violations, price controls and lack of transparency remain major obstacles to U.S. medicines. Industry concerns are addressed through bilateral meetings between U.S. and Chinese government officials in Beijing and Washington, through written correspondence

and in bilateral forums designed to support US companies' interest in engaging the Chinese government on issues that ultimately will influence their ability to access the Chinese market.

U.S. pharmaceutical companies note that China's failure to protect intellectual property rights poses a serious public health risk and undermines the competitive advantage innovative companies gain from their substantial investments in research and development. The industry estimates that it loses between 10-15 percent of its annual revenue in China to counterfeit products. American pharmaceutical companies have taken an active and cooperative approach in trying to reduce the production and distribution of counterfeit pharmaceuticals in China. Many companies have joined the Quality Brands Protection Committee, in which participant companies conduct market sampling and surveillance, as well as raids on suspected counterfeit manufacturers and distributors. U.S. pharmaceutical companies seek to work with the U.S. and Chinese governments to eliminate counterfeit pharmaceuticals and urge both countries to make this a high priority. The Commerce Department has held numerous technical assistance seminars on IPR enforcement throughout China and has raised the issue with senior Chinese government officials.

As a result of these efforts, at the Joint Commission on Commerce and Trade meeting on April 21, chaired by Secretary Evans and Ambassador Zoellick on the U.S. side and China's Vice Premier Wu Yi, China announced a series of significant steps to strengthen its protection of intellectual property rights, including for pharmaceutical products. These include a commitment to achieve a substantial reduction in IPR infringement through increased enforcement efforts and a reduction in the thresholds for criminal prosecutions of IPR violators. We will continue to monitor progress on these commitments and work with China to ensure their implementation. We have established a bilateral IPR working group to maintain a focus on these efforts. Through the working group we will also seek to address individual IPR cases brought to us by our companies and develop additional avenues to strengthen China's protection for pharmaceutical and other intellectual property.

The US-China Healthcare Forum is being developed by the Department of Commerce and its Chinese counterparts to enhance cooperation in the areas of healthcare policy; to improve China's ability to provide effective, sustainable, high quality healthcare services to its people; and to support US companies' interest in engaging the Chinese government on issues that ultimately will influence their ability to access the Chinese market.

For much of the last decade, China has been wrestling with the problem of reforming its centrally planned healthcare system. Following the onset of SARS, the White House announced enhanced cooperation with China in battling this and other infectious diseases. However, most of these efforts have focused on the medical/technical aspects of the problem, for example, increased training of medical workers, cooperative research programs and donations of medical equipment.

Though important, these steps represent only a part of the puzzle. High tech equipment and innovative pharmaceuticals are of limited value unless China has a comprehensive system for efficiently delivering healthcare services to its vast population. Developing such a system will require a much larger private healthcare sector.

In response to these issues, Secretary Evans and Secretary Thompson (HHS) jointly proposed in a letter to China's Vice Premier Wu Yi that the U.S. and China develop a high-level dialogue to focus on the economic aspects of healthcare delivery. China accepted, and together with industry, we have planned a two-day program in Beijing (May 27 and 28) that will feature senior government officials and industry representatives from China and the United States. The discussion will focus on ways of making the provision of healthcare sustainable and efficient, methods for developing a transparent, objective and science-based approach to regulation of healthcare products and services, and how to foster a system that rewards innovation and promotes the continuous upgrading and modernization of the healthcare system.

We hope this forum will provide U.S. industry an opportunity to engage Chinese policy makers on issues that impact their ability to access the Chinese market as well as expand the dialogue between healthcare providers in the U.S. and China.

B. Japan: Pharmaceuticals/Medical Equipment

The United States Government (USG) has been using an advocacy approach to encourage Japan to adopt policies that reward American firms' intensive research and development, which prompts production of the world's most innovative medical devices and pharmaceuticals. Japan's population is rapidly aging, which is draining financial resources from the national health insurance system and creating pressure for spending cuts. This pressure is particularly strong in the medical device and pharmaceutical sectors.

The USG meets several times a year with Japan's Ministry of Health, Labor and Welfare in the U.S.-Japan Working Group on Medical Devices and Pharmaceuticals and has raised concerns about Japanese reimbursement policies. This Working Group is part of two bilateral mechanisms – the 1986 bilateral agreement known as Market-Oriented, Sector-Selective (MOSS) and the Regulatory Reform and Competition Policy Initiative, which is part of the Economic Partnership for Growth ("Partnership") created by President Bush and Prime Minister Koizumi in 2001.

USG's advocacy in this Working Group has contributed to reimbursement pricing reforms in Japan that have been gradually leveling the playing field for U.S. companies. U.S. efforts to date have resulted in substantial savings for American medical device and drug firms, which previously faced unfair reimbursement price cuts. Japanese patients have also benefited by gaining access to innovative products that save money in the long run and can reduce the length of hospital stays.

C. South Korea: Establishment of a Health Care Working Group

The South Korean government has traditionally prevented foreign drug companies and other key health care stakeholders from providing input before policies are adopted. Such actions have adversely affected U.S. pharmaceutical companies. The U.S. government has responded, focusing on increasing transparency in government pricing and regulatory policies.

In pursuing this goal, the U.S. government proposed – and South Korea’s government agreed to – establishing a bilateral health care reform working-group in January 2002. The group provides a forum for foreign drug companies to discuss South Korean governmental proposals and health care reform. The U.S. has urged Korea to keep using the Working Group, whose work is ongoing, as a way to disseminate information.

D. Taiwan: Lack of Data Exclusivity Regime for Pharmaceuticals (IPR)

Taiwan was required to put into place a TRIPS-level intellectual property protection regime, as a condition of WTO membership. Taiwan, unfortunately, still has not revised its legislation to meet the data protection obligation of TRIPS Article 39.3, the provision that directly affects the pharmaceutical industry.

Under Article 39.3, WTO member governments are required to: (1) protect against “unfair commercial use,” and (2) not disclose the data that the pharmaceutical manufacturers give governments in order to gain market approval for their innovative drugs. This article is understood worldwide to mean that governments must prevent regulators or third parties from relying on data provided for market approval to market later versions of the drug during a period of exclusivity – unless the originator grants consent.

The U.S. government is working with Taiwanese officials to ensure full compliance with this Article. Discussions are continuing through regular bilateral trade talks.

E. Hungary: Pharmaceutical Pricing Regime

The Department of Commerce is currently working with the American pharmaceutical industry to reverse a Hungarian government policy that unilaterally cut the price for pharmaceuticals by 15 percent. Secretary Evans received a commitment from the Hungarian government to establish a working group with the U.S. pharmaceutical industry that will examine the situation. This working group would help the Hungarian Government develop a pricing policy that provides adequate medical coverage for the public and supports innovation in the pharmaceutical sector. We have commitments from the Hungarian government that the working group will meet soon.

This is important because, on March 8, 2004, the Hungarian Ministry of Health informed both Hungarian and foreign pharmaceutical companies, that individual companies had four days to agree to return 15 percent of total turnover from reimbursed products to Hungary’s government. If companies did not agree, the Ministry of Health would cut drug prices by 15 percent on April 1, 2004. Since only five percent of companies active in Hungary’s pharmaceutical market signed the agreement, the remaining 95 percent have received 15 percent cuts that began April 1. The domestic and foreign pharmaceutical companies in Hungary have appealed to the Constitutional Court in hopes of obtaining a reversal.

In September 2003, the Hungarian government issued a similar order, threatening to cut prices by 20 percent if companies did not return partial turnover from reimbursed products. This price cut was avoided through a negotiated settlement. The staff of the local U.S. embassy fears that the Minister of Health believes this forced repayment system is a viable, enduring solution to Hungary's budgetary woes and could use such tactics annually. Secretary Evans and Department staff members have encouraged the Hungarian government to resolve this problem through a working group with the pharmaceutical industry.

F. Brazil: Patent Approval Delays

Commerce is leading an interagency effort to provide technical assistance to patent examiners at the Brazilian Patent Institute (INPI) and my colleague, Jon Dudas, Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the U.S. Patent and Trademark Office, can describe how the PTO is helping provide technical assistance to Brazil's National Patent Institute to resolve the backlog of pending trademark applications.

Brazil's difficulties in granting patents and trademarks continue to worsen, as INPI lacks much needed resources and the involvement of the Ministry of Health's Sanitary Surveillance Agency (ANVISA) in pharmaceutical patents has become more pronounced. The Lula Administration's industrial policy goals focus on improving the technological base of Brazilian industry with special emphasis on software and pharmaceutical industries, has spotlighted INPI. The 2004-2007 Pluriannual Plan announces the objective of reducing patent processing time from seven years to four, and from four years to one for trademarks.

There appears to be recognition within the government of Brazil that the INPI/ANVISA joint review has negatively affected approval for pharmaceutical products or processes, but no remedies have been offered. INPI's staffing woes should be ameliorated somewhat this year, with 108 new patent examiner positions available to qualified civil servants, and Ministry officials expect a permanent president of INPI to be named shortly.

I intend to travel to Brazil during the last week of May on a trade policy mission. During this trip, I will meet with the regulatory agencies that oversee pharmaceutical patents and trademarks and convey USG concern about problems encountered during the approval process and to press for the resolution of those issues.

G. Mexico: Protection of Pharmaceutical Patents

Commerce was instrumental in helping to achieve protection of pharmaceutical patents in Mexico. The U.S. pharmaceutical industry reported that Mexico's Ministry of Health was granting marketing approval of pharmaceutical products without checking with the Intellectual Property Institute (IMPI) for valid patents on the products. The lack of coordination between the Ministry of Health and IMPI had the potential to inflict losses of approximately \$10 million for U.S. firms who owned the Mexican patents. Following significant U.S. government advocacy, President Fox signed a decree that requires the Ministry of Health to check with IMPI for valid patents before granting marketing approval.

H. Other Monitoring and Enforcement Approaches

Beyond these advocacy efforts we also have the opportunity through the annual "Special 301" review led by USTR to identify countries that deny effective protection of intellectual property rights or equitable market access for Americans dependent on intellectual property protection. Pharmaceutical Research and Manufacturers of America (PhRMA) member companies are important contributors to the Special 301 process. This annual review of countries' actions, or lack thereof, to protect IPR is often an effective means to get results. Many trading partners are motivated by their potential placement on our lists to take action and resolve our concerns such as protection of data and enforcement against counterfeit drugs.

And of course, on a daily basis, Commerce Department staff are monitoring foreign countries' compliance with trade agreements, including TRIPs, and ensuring that these issues are raised with foreign counterparts in every opportunity from travel to foreign capitals or in our bilateral meetings here in Washington.

V. Getting Policy Climate Right to Promote Innovation

Mr. Chairmen, I have described our efforts to promote and protect U.S. intellectual property rights around the world, but we do not do this just because our innovative industries deserve that support. We recognize in the United States that solid protection of intellectual property is essential to our ability to maintain a research-based pharmaceutical industry that promotes innovation, inspires creativity, achieves breakthroughs in life-saving medicines and enhances quality of life. A positive climate that fosters innovation has spillover effects well beyond pharmaceuticals.

Americans benefit from the fact that foreign firms recognize and value this climate in the United States. Swiss drug development giant Novartis announced plans to establish the Novartis Institute for Biomedical Research Inc. (NIBRI) in Cambridge, Massachusetts, in 2002. The project, which is valued at \$250 million and brought 400 jobs to Cambridge, created a new center for its worldwide research activities. Novartis CEO Daniel Vasella also announced that NIBRI would hire an additional 1,000 researchers and scientists over the next five years. According to press reports, Novartis chose Cambridge for its scientific talent pool, high-quality academic base, and comparative proximity to Europe. Like many other foreign-based firms, Novartis has found American universities, policy, and markets as highly conducive to drug development.

Let me give you a few examples of what can happen when governments fail to take these considerations into account in setting policy. In 2004, Pfizer announced it planned to close its facility in Freiburg, Germany. Pfizer's decision was largely due to Germany's plans to limit market access for innovative drugs. The new reimbursement and pricing policies would categorize innovative drugs identically to twenty-year-old generic drugs, for pricing and reimbursement purposes.

A November 2000 report prepared for the Directorate General Enterprise of the European Commission found that European industry has been losing its competitive edge, when compared to the United States. Although there are differences across various European countries, Europe as a whole lags behind in its ability to generate, organize, and sustain innovation processes that are increasingly expensive and organizationally complex.⁷

The need to get the policy environment right means encouraging the use of market-based mechanisms to set prices and relying on the market both to reward real innovation and to expand the market for generic products that set the outward bounds on pricing. Nowhere is that more important than in the case of Canada. Unlike many other countries, Canada uses a system of international price comparisons that disregards valid reasons for cross-border price differences.

On behalf of our pharmaceutical industry, we have consistently argued that using international price comparisons and price ceilings on patented medicines is inappropriate and does not bolster quality health care. Plainly, addressing the issues our industry confronts under the Canadian system is an essential step in ensuring that both prices in the North American market reflect the risk our firms take on in developing new and innovative medicines and the true cost to the consumer of providing those benefits to the market.

One way to improve our advocacy of changes in the policy environment, particularly among OECD countries, is to gain a clearer understanding of the facts. That is one reason I welcome the opportunity provided by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 to examine the drug pricing practices of other OECD countries, including Canada, Europe, and Japan. The report has been undertaken in consultation with the Department of Health and Human Services, the Food and Drug Administration, the International Trade Commission, and USTR. We have coordinated closely with the FDA on our data needs, focusing our efforts on a comparison of pricing between the United States and 9 other OECD countries.

I am hopeful that our findings will provide further elaboration on the issues and will point out gaps in our collective knowledge while providing additional information in order to understand better the economics of this complex market. We intend to present the final report to Congress within the congressionally mandated deadline.

In looking at this issue, the OECD itself has begun work aimed at finding ways to improve health care system performance. In my view, the OECD efforts create yet another avenue for our advocacy. We will look to the OECD to help in rounding out our understanding of the impact that pharmaceutical pricing systems have on innovation and ultimately on the availability of quality healthcare at the lowest possible cost to all Americans and the citizens of our trading partners abroad.

⁷ Alfonso Gambardella, *Global Competitiveness in Pharmaceuticals – a European Perspective*.

Mr. Chairman, that concludes my remarks. Thank you again for the opportunity to testify before you today. I would be pleased to answer any questions you may have.

RESPONSE TO A QUESTION FROM SENATOR GRASSLEY

Question 1. I was disturbed by a recent article published in the April 27th edition of *The Washington Post* in which it was alleged that the Administration has not been effectively enforcing international trade agreements. As Chairman of the Finance Committee I am deeply concerned about effective enforcement of our international trade agreements.

I have attached the article, along with the report and speech upon which the article is based, for your review. Is the article and the material upon which it is based accurate? If not, please describe which aspects of these materials are inaccurate. Also, please outline what steps the Administration has taken and is taking to effectively enforce our international trade agreements.

Answer. This Administration is strongly committed to ensuring that our trading partners fully comply with their trade agreements with us, and that our businesses, workers, and farmers get the full benefits of the agreements we negotiate on their behalf. To this end, the Commerce Department participates in the interagency effort to actively monitor and enforce foreign country compliance with our international trade agreements. Secretary of Commerce Donald Evans has emphasized that monitoring and compliance are the highest priority for all units within the International Trade Administration.

We seek to resolve trade barriers before they become formal disputes. The scope of the Administration's enforcement activities, therefore, extends well beyond the number of cases brought before the WTO or NAFTA tribunals. While formal dispute settlement is sometimes the only way to ensure that trade commitments to the United States are upheld, the most timely and effective way to achieve enforcement goals is through other means. In fact, the vast majority of enforcement efforts are brought to successful resolution without the need to resort to formal litigation.

A variety of mechanisms are employed to actively seek out compliance problems and resolve them before they become disputes. Commerce, USTR, and the various trade agencies and offices work to consult and negotiate solutions at the most effective level, applying numerous incentives and disincentives to persuade our trading partners of the benefits of compliance with their trade obligations.

A good example of the value of multi-pronged enforcement efforts is the Administration's recent success in assuring that China is meeting its WTO commitments. Given the number of pressing bilateral issues this year, Secretary of Commerce Evans and U.S. Trade Representative Zoellick co-chaired this year's Joint Commission on Commerce and Trade, and Secretary of Agriculture Veneman also participated. In the course of these April 2004 meetings, the Administration was able to resolve seven potential WTO cases involving high-technology products, agriculture, and intellectual property protection that will benefit U.S. manufacturers, high-tech workers and farmers.

We also participate in negotiating new agreements such as free trade agreements and Commerce brings to the table experience in working with business and using the negotiations to resolve problems we know about in particular markets. For example, an issue involving Australian standards on medical products was successfully resolved by keeping an open dialogue with Australia during FTA negotiations.

At Commerce, a vital aspect of our compliance programs is outreach, to let U.S. exporters know that the government can help address many of the problems they face in foreign markets. The Department uses as many government and private sources as possible as "nets" to actively search for problems. The Department's Trade Compliance Center (TCC) actively searches for instances in which foreign countries are not living up to their trade obligations, and maintains the Department's "Trade Complaint Hotline," www.export.gov/tcc/hotline, where U.S. businesses can register their complaints online. The *TCC On-Line* website, also at www.export.gov/tcc, is a free service that provides the business community with proven tools to maximize export opportunities.

The TCC also coordinates our Compliance Liaison Program, which is a public/private partnership of trade associations, Capitol Hill staff, state level counterparts, and local business export councils to facilitate communication and prompt action on compliance issues. Compliance Liaisons work with the TCC to refer constituent market access or compliance problems.

Ensuring our trade rights requires systematic follow-up, and we are making every effort to do so. Each trade agreement is assigned a Designated Monitoring Officer (DMO), whose responsibility is to actively monitor compliance with the assigned agreement. We have put in place special monitoring programs for China, Korea and Japan and placed four Compliance Officers on staff at our embassies in China, Japan and at our mission to the European Union in Brussels. We also learn about potential problems from all different parts of the Department, including a worldwide

network of 150 posts in 78 countries and 107 Export Assistance Centers throughout the United States, our industry and country desks, and trade agreement specialists.

The Office of Textiles and Apparel (OTEXA) works to ensure that all agreements include tough rules of origin and anti-circumvention language. OTEXA, through the Committee for the Implementation of Textile Agreements (CITA), is responsible for penalizing factories and countries for illegal transshipment. CITA cooperates with U.S. Customs and Border Protection (CBP) on enforcement efforts. CITA also takes textile and apparel safeguard actions, when appropriate, under the World Trade Organization (WTO) Agreement on Textiles and Clothing (ATC) and the North American Free Trade Agreement.

Building upon its monitoring efforts, the Administration's enforcement strategy seeks to maximize the benefits of our trade agreements. When the Department receives a trade complaint, an expert team is formed to investigate and analyze the problem. The compliance team examines the provisions of relevant trade agreements, consults with appropriate interagency staff, and develops a compliance strategy to resolve the issue. Our compliance program employs an active case management system to track and investigate compliance complaints. This database is available to domestic Commercial Service offices and overseas posts.

Compliance teams seek to develop convincing positions aimed at persuading foreign countries to comply with their obligations, short of formal dispute settlement. Whenever possible, we try to prevent trade agreement compliance violations before they start and attempt to resolve disputes by persuading parties to come into compliance voluntarily.

Our approach has had considerable success, many benefiting small- and medium-sized companies. Some examples of successes include:

- Following the April 2004 meeting of the U.S.-China Joint Commission on Commerce and Trade (JCCT), Chinese officials suspended implementation of its mandatory wireless encryption standard indefinitely, which had raised serious questions of national treatment as well as technology transfer concerns. China agreed to revise this standard and participate in international wireless encryption standard bodies.
- Compliance staff in Washington and China worked with a major U.S. software company to ensure fair and WTO compliant treatment by Chinese authorities in its valuation of software. After the Commerce team arranged for the company to meet with China customs and explain its business in November 2003, the company was not required to pay \$7 million in supplemental duties.
- Due to U.S. government efforts, China changed its end use certification requirement for certain information technology products and joined the WTO Information Technology Agreement. Over \$3 million in exports were at stake.
- U.S. officials raised the issue of India's high textile tariffs and additional taxes, which raised transparency and potential national treatment concerns, with Indian officials at several high-level meetings. Subsequently, on January 9, 2004, India reduced the customs tariff on imports of most non-agricultural goods from 25 to 20 percent and eliminated a 4 percent Special Additional Duty. Approximately \$500 million in potential U.S. textile exports were affected by the taxes.
- Following U.S. government advocacy, President Fox of Mexico signed a decree that requires the Ministry of Health to check with the Intellectual Property Institute (IMPI) for valid patents before granting marketing approval for pharmaceuticals. The U.S. pharmaceutical industry had reported that Mexican officials were granting marketing approval of pharmaceutical products without checking for valid patents on the products, thereby costing U.S. pharmaceutical companies around \$10 million.
- In January 2004, Egypt lowered rates on certain textile and apparel items to the bound rates Egypt accepted during the Uruguay Round negotiations. This action followed an Administration request for formal consultations with Egypt at the WTO in Geneva in December 2003, as well as various meetings, including between former Commerce Deputy Secretary Bodman and Egyptian officials. As much as \$30 million in U.S. exports could have been at stake.
- As a result of work led by Commerce, Bangladesh Customs no longer subjects a North Carolina company to unfair customs valuation treatment. The company exports about \$2 million worth of tire cord fabric to Bangladesh per year.
- As a result of USG advocacy, the Tanzanian government adopted many of the textile regulation revisions requested by U.S. industry. The United States exports about \$7 million of used garments to Tanzania per year.

At Commerce, we are looking for new ways to ensure compliance with our trade agreements and help U.S. exporters. ITA is creating a new Investigations and Compliance Unit to ensure compliance with our trade agreements and combat violators of IPR around the world. An individual with a prosecutorial background will lead

the unit, assisted by a team of experts. The new unit will pursue perpetrators along the entire chain, including manufacturers and importers, and will exert pressure on countries where problems are found. It will work with U.S. industry and coordinate with other U.S. agencies, including PTO, to investigate allegations of piracy and help develop trade compliance cases.

We are also working to form and launch the Unfair Trade Practices Task Force. This task force will enhance and more effectively focus existing Department of Commerce resources to identify and challenge a wide range of unfair foreign government practices. By identifying and rooting out distortive trade practices, whether through advocacy, negotiation, or legal action, the Administration seeks to free U.S. firms and workers from unfair competition.

The vast majority of U.S. compliance efforts are conducted successfully by pressing foreign governments directly through a variety of interagency channels. When necessary, however, we work with USTR to build a strong case for formal dispute settlement actions. For example, the Administration was not confident that repeated efforts to urge China to remove a discriminatory tax on U.S. semi-conductors were bearing fruit. Accordingly, the United States filed the first-ever WTO case against China. As a result of consultations conducted under dispute settlement procedures, the United States and China agreed on a resolution to the dispute that will ensure full national treatment for U.S. integrated circuits in China, the world's fastest growing semiconductor market and an export market worth over \$2 billion to American manufacturers. Whenever possible the Administration endeavors to reach favorable settlements that eliminate foreign violations of our trade agreements without engaging in prolonged litigation. In fact, we have resolved 22 of the cases we've brought at the WTO without litigation.

There are situations, however, when enforcement can only be achieved through litigation. When such cases arise, the United States has a long record of litigating both aggressively and successfully. The United States has brought more cases (71) at the WTO than any other country. Of those proceedings, we've won on the core issues in 22 cases, resolved 22 in our favor without litigation, and did not prevail on the core issues in only 3 cases. The remaining cases are still in litigation, consultations or otherwise inactive.

It is important to note that fewer cases are currently being brought by all countries in the WTO than in the past. There were just over half as many cases brought in 2003 (28) than in the peak year of 1997 (46). This reflects both the pent-up demand among all countries to bring cases immediately following establishment of the WTO and the adoption of the Understanding on Rules and Procedures Governing the Settlement of Disputes, as well as the successful deterrent effect of formal dispute settlement proceedings. This trend is particularly evident with regard to the most active members of the WTO in terms of using WTO dispute settlement, the United States and the European Union. Both have been complainants and respondents in roughly the same number of cases every year.

RESPONSES TO QUESTIONS FROM SENATOR KYL

Question 1. The U.S. is hosting the G-8 Summit this summer. Several members of Congress strongly believe that the issue of pharmaceutical price controls should be added to the Summit agenda; that we simply cannot let this opportunity go by without raising the issue. While I understand that the National Security Council is charged with developing the agenda for the meeting, will you be able to work with the NSC to add this issue to the agenda?

Answer. We worked with the NSC and USTR to propose the formation of a G8 working group on life sciences innovation prior to the launch of the June meeting at Sea Island. Our goal was that, if agreed to, the working group would provide us with a central focal point for discussions about aspects of our policies that are most consistent with fostering life sciences innovation, and conversely, those practices that could stifle life sciences innovation or inhibit the availability of innovative life sciences goods and services. Unfortunately, the proposal for work on this issue was not a topic that drew wide support from other members of the G8, which as you know, operates by consensus. We will continue to look for other international opportunities to raise the importance of promoting market dynamism and fair and effective competition for life sciences goods and services.

Question 2. I am told that Japan continues to unfairly reduce reimbursement for medical devices based on non-transparent criteria such as foreign average price adjustments, a type of reference pricing. What can the Commerce Department do to address this problem?

Answer. Commerce will continue to strongly and consistently oppose any unfair reductions in reimbursement prices for medical devices in Japan by raising our con-

cerns in bilateral meetings and letters. This issue is one of our top priorities. In December, Secretary Evans wrote to both the Chief Cabinet Secretary and the Minister of Health, Labor and Welfare to express concern that Japan would reduce prices for medical devices in a way that would harm U.S. companies disproportionately. In his letters, Secretary Evans specifically called attention to the Foreign Price Adjustment rule that you mentioned. Secretary Evans also raised this issue in letters to Japanese Government officials in November and in meetings with them in October 2003 in Tokyo. Assistant Secretary for Market Access and Compliance William H. Lash, III wrote to his Health Ministry counterpart in October to reiterate our opposition to the Foreign Price Adjustment rule. This was followed in December 2003 by a similar letter to the Ministry of Foreign Affairs by Deputy USTR Josette Shiner. We will continue such efforts at the highest levels as well as at the working level in the U.S.-Japan Medical Devices and Pharmaceuticals Working Group. The Commerce Department chairs this Working Group, which is part of the USTR-led Regulatory Reform and Competition Policy Initiative under the U.S.-Japan Economic Partnership for Growth (agreed to by President Bush and Prime Minister Koizumi in 2001). Commerce expressed opposition to the Foreign Price Adjustment rule at the most recent Working Group meeting in May in Tokyo. We plan to voice our concerns in the coming year during regular meetings of the Working Group under the Regulatory Reform and Competition Policy Initiative.

RESPONSES TO QUESTIONS FROM SENATOR GRAHAM

Question 1. The March 1, 2004 Draft of Annex 2-C of the Australia Free Trade Agreement covers pharmaceuticals. The document applies to federal healthcare programs in that it includes the terms “federal healthcare authorities”, “federal healthcare programs”, and “federal healthcare agencies”. I would like clarification as to whether there are any existing or future U.S. programs that could be subject to the Annex. Please clarify for me which, if any U.S. agencies or programs that provide or arrange for coverage of prescription drugs (including, but not limited to Medicare, Medicaid, VA, DOD, or any state operated pharmaceutical assistance program) would be exempted from the Annex through the footnote relating to procurement and which would be subject to the Annex. For example, the Medicare program currently covers many drugs under Part B of the program. The Medicare program determines which drugs are covered, and the reimbursement level, but does not actually procure the drugs. It seems to me that Medicare’s decisions regarding Part B drugs would thus be subject to the Annex. Is that correct? I would like an answer that responds specifically to each of the federal programs providing or reimbursing for pharmaceuticals, directly or indirectly, as well as for state programs that are wholly state financed and operated and those that are partially federally financed. Please reference the specific language in the draft agreement that clarifies which policy—the annex or the procurement chapter—applies to which agencies, programs, or activities.

Could any future U.S. federal program that uses federal ceiling prices, Federal Supply Schedule pricing requirements, or any federally-determined reimbursement system, or any state pharmaceutical assistance program including those that are partially financed through federal dollars be subject to the Annex? Please respond to this question both in terms of programs that would have the federal government actually taking ownership of the drugs, as well as any program in which the federal government wholly or partially made payment for the drugs, but did not actually possess the drugs at any time.

Answer. Procurement of pharmaceutical products by VA and DoD is excluded from operation of the Annex by footnote 1. Procurement of pharmaceutical products by state Medicaid agencies is excluded from the operation of the Annex because coverage and reimbursement decisions are made by state officials, not by Federal health authorities. The Annex may apply to certain reimbursement decisions concerning pharmaceuticals under Part B, and current Medicare practice is consistent with the Annex. As it has been established, Medicare, Part D, which will take effect in 2006, will not be covered by the Annex since coverage and payment decisions are not directly made by the Federal health authorities.

The applicability of the Annex to future programs would depend on how they were structured. If the Federal government procured the drugs, the Annex would not apply (footnote 1). If private parties or state officials made the coverage and payment decisions, the Annex would not apply. Federal matching payments to a state for the purchase of a pharmaceutical product does not render the Annex applicable.

Question 2. Please clarify the terms “pharmaceutical formulary development and management” (which appear to be subject to Chapter 15) versus “decisions regarding payment and coverage” or “procedures for listing of new pharmaceuticals or indi-

cations or for setting the amount of reimbursement for pharmaceuticals” (which appears to be subject to Annex 2-C).

Answer. The Annex and accompanying documents do not contain a definition of the terms referred to. However, the development of a formulary is generally a part of the decisions relating to the listing of pharmaceuticals or indications for reimbursement purposes. Formulary management also would include promulgating and implementing usage guidelines, negotiating contracts and incentive agreements, actively managing utilization, and other related activities.

Question 3. Could Annex 2-C be interpreted to apply when VA uses the formulary to make decisions regarding payment and coverage, even though actual management and development of the formulary would be subject to Chapter 15 and not Annex 2-C?

Answer. When the VA uses a formulary to make decisions regarding payment and coverage, this is considered to be part of government procurement by the first sentence of footnote 1 and thus excluded from the operation of the Annex, but subject to Chapter 15 on Government Procurement.

RESPONSES TO QUESTIONS FROM SENATOR LINCOLN

Question 1. Is there any evidence that prices in countries like Canada and Australia (who use their governments to negotiate prices) are lower than what the private sector in the United States can negotiate?

Answer. According to PhRMA, the U.S. pays more for pharmaceuticals on a per unit basis than several countries with national health programs, including Canada, Italy, France, the UK, Sweden, Germany and Switzerland. According to John Calfee of the American Enterprise Institute, whose testimony you heard earlier, America’s \$126 billion annual expenditure on non-government prescription drugs is far larger than the entire pharmaceutical market in any single European nation (Germany’s being the largest at \$20 billion) or the entire Japanese market, the second largest in the world at \$53 billion.

Question 2. The international market for pharmaceuticals and the determination of prices across countries in the global market are influenced by a number of factors. One key factor is the large cost of R&D, which is global in nature. R&D expenditures remain the same regardless of how many consumers or countries are served by the product. Because these costs cannot be easily attributed to any particular consumer or country, the pharmaceutical industry faces the problem of how to assign costs to the different countries they serve. What can we do about this? Should we enter into a discussion with countries with high R&D expenditures to make drug prices more equitable or work together to reduce costs and provide incentives for developing new medicines? Do we need new global accounting methods to assign costs?

Answer. It is not clear that drug prices in the United States are directly affected by prices in other markets. Academic literature as well as testimony at the April 27 hearing by non-government experts suggests that higher prices abroad would not necessarily affect prices in the United States.

The area of most concern appears to be the impact of pricing controls on R&D and innovation. Industry has strongly maintained that price controls are less conducive to R&D and innovation than a free market system for drug pricing. Certainly, the figures support that conclusion. The U.S. has been producing new drug substances at sustained rates since 1985, while over the same period output among Germany, France and the UK has plummeted (Robert Goldberg, Manhattan Institute). The U.S. is the leader in biotechnology, holding 70% of all genetic engineering patents worldwide, and 72% of all biotech revenues come from U.S. companies (Goldberg). American citizens have not only benefited from these new medicines, which target such diseases as cancer, heart disease, and stroke, but have benefited from the decline in hospitalization costs, fewer missed work days and other savings. Moreover, since 1990, the pharmaceutical industry has grown twice as fast as the overall economy. The industry is a significant source of new, highly skilled jobs and is one of the nation’s largest employers, with approximately 223,000 employees nationwide (PhRMA Industry Profile 2003).

The Administration has been pursuing issues related to market access and intellectual property in our Free Trade Agreements (FTAs) and other negotiations. In our Australia FTA, we obtained commitments from Australia to ensure greater transparency and accountability in this drug reimbursement pricing decision process. We are currently considering what additional steps we might take.

Question 3. Will removing international barriers and pursuing market access for pharmaceuticals result in lower prices for U.S. consumers? Will it help the private insurance companies in the U.S. negotiate lower prices?

Answer. In the near term, increased market access and increased overseas sales are not likely to impact significantly on prices in the United States. However, a number of studies point to the connection between revenues, profits, and R&D and the effects of higher R&D on innovation. Thus, there could be significant benefits in the longer term with increased competition and more new drugs, which could lead to significant savings from lower hospitalization costs, fewer missed work days and other factors.

There are studies that indicate drug prices in a number of developed countries have been lower than in the United States. Competition in the U.S. market generated by the new Medicare drug discount cards program already has resulted in reductions off retail prices for both brand-name and generic drugs.

Question 4. How will trade agreements that provide more market access to the U.S. pharmaceutical industry impact the VA National Formulary, the Medicaid Supplemental Rebate Program, and future attempts to enable Medicare to get the best prices for drugs?

Answer. USTR has been working closely with the VA, DOD, HHS, FDA and other relevant agencies to ensure that U.S. trade agreements would not impact the ability of any of these programs to get the best prices for drugs. The Pharmaceutical Annex to our FTA with Australia, for example, specifically excludes government procurement of pharmaceutical products, including pharmaceutical formulary development and management for federal healthcare agencies. Programs that are implemented at the state level, such as Medicaid programs, are not covered by the Pharmaceutical Annex.

U.S. agencies already comply with the requirements of the Government Procurement Chapter of the Australia FTA because the United States is a party to the WTO Government Procurement Agreement. However, since Australia is not a signatory to the WTO GPA, the FTA opens new opportunities to both Australian and U.S. firms.

Question 5. Although many consider pharmaceuticals to be a cost effective tool to treat and, in some cases, reduce the disabling effects of many health conditions, as well as possibly reducing the need for hospitalization, many countries are increasingly seeking ways to contain costs related to national consumption of pharmaceuticals. What are we doing in the United States in this regard?

Answer. Pharmaceutical products in the United States are in large part purchased in a private, competitive market. This provides the best mechanism for balancing the price and value of each drug to consumers. In recognizing value, the market provides economic incentives for innovation and the development of new drugs. The fact that drugs are purchased in a competitive market (or the purchases are funded) by people who have an economic stake in the purchase has led to a number of market responses that have the effect of lowering drug prices from what they would otherwise be: Pharmacy benefit managers developed to consolidate purchasing power and provide services to consumers have reduced prices. The new Medicare drug discount card is lowering prices through a similar mechanism. And purchases of drugs under the new Medicare Part D by prescription drug plans will similarly provide the benefit of aggregated purchasing power.

The United States is unique among industrialized countries in providing both strong incentives to create new pharmaceutical products and also generating significant cost savings on proven drugs through highly competitive generic markets after patent expiration. This dual approach has led to generic drugs accounting for a larger proportion of drug purchases (and at lower prices relative to the patented medicines) in the United States than in countries that do not have market-based systems. The United States also has enacted statutes designed to reduce drug prices for certain purchasers, including the Medicaid rebate program (although competition often results in prices lower than those that would be possible under the Medicaid rebate program) and the Federal Supply Schedule for purchases by the Federal government and others who are permitted by statute to buy at the FSS prices (it should be noted that the FSS relies in large part on negotiated prices in a competitive market).

Question 6. A recent report from the Institute of Medicine reveals that the VA National Formulary is not more overly restrictive "than other public or private formularies." It also "rarely designates drugs or drug classes as absolutely excluded or requires prior authorization of drugs as managed care formulary systems frequently do, nor does it impose tiered co-payments as is often the practice in managed care." Also, only 0.4% of veteran complaints could be attributed to the VA Formulary. Do you know how citizens in other countries such as Australia feel about their national health system's pricing system? Do they feel that it is fair in ensuring access to medically-necessary drugs?

Answer. You are correct in pointing out the relatively high satisfaction rate among enrollees of the Veterans Affairs National Formulary (VANF) plan. The point of VANF and similar strategies is to attempt to ensure fair and rational allocation of health care resources through a systematic and explicit process on a national scale and, as you have pointed out, many believe that the program is a success.

It is our understanding that Australians support the national health care system. However, there are reports that indicate views in Australia differ about the process for listing and pricing new drugs on the Pharmaceutical Benefits Scheme formulary and its impact on the ability of Australian citizens to gain timely access to the most innovative and “medically-necessary” drugs.

Question 7. My understanding of the Australian reference pricing system is that if a drug is truly innovative, it will be paid for appropriately. How does the Australian reference pricing system ensure that patients have access to innovative drugs?

Answer. The Australian Government uses a reference pricing system to control the cost of pharmaceuticals it covers under its Pharmaceutical Benefits Scheme (PBS). While there is no annual budget limitation on PBS expenditures, Australian government officials acknowledge that the expected annual cost of each new drug is a factor in determining PBS listings. Indeed, Australian government studies have raised concerns about the availability of new drugs or new applications of drugs already on the PBS and have suggested alternative ways of increasing availability of new drugs to Australian patients.

Mr. Chairman, members of the Senate Finance Committee, and fellow panelists, my name is Gerard Anderson and I am a professor in the Bloomberg School of Public Health and a professor of Medicine in the School of Medicine at Johns Hopkins University.

In my testimony this morning I will make five points:

- First, other industrialized countries, have committed considerable political capital and developed sophisticated programs to determine the appropriate use of pharmaceuticals and to control pharmaceutical prices. The U.S. has not.
- Second, our analysis shows that the U.S. pays twice as much for a market basket of 30 commonly prescribed pharmaceuticals as other industrialized countries.
- Third, if other countries paid more for pharmaceuticals; prices in the U.S. would not necessarily go down.
- Fourth, the attempt by the U.S. trade representative to encourage other countries to raise their pharmaceutical prices suggests that there is one single price that all industrialized countries should pay. Enforcing this policy would lead to pharmaceutical price fixing on an international scale.
- Fifth, the U.S. should use prices in other countries as a benchmark for the prices it pays for pharmaceuticals, especially in the Medicare program. Lower prices for pharmaceuticals would improve access to pharmaceuticals and could be used to eliminate the "doughnut hole" in the Medicare program.

Cost Comparisons

An article I coauthored last year in Health Affairs entitled "Its Prices, Stupid: Why the United States Is So Different From Other Countries" explains that compared to other industrialized countries, the U.S. pays considerably more for all health care goods and services, including drugs. I have attached the full article to my testimony and have included the final paragraph of the article in my testimony here:

"In 2000 the United States spent considerably more on health care than any other country, whether measured per capita or as a percentage of GDP. At the same time, most measures of aggregate utilization such as physician visits per capita and hospital days per capita were below the OECD median. Since spending is a product of both the goods and services used and their prices, this implies that much higher prices are paid in the United States than in other countries. But U.S. policymakers need to reflect on what Americans are getting for their greater health spending. They could conclude: It's prices, stupid."

The data presented in the article show that the U.S. pays twice as much per capita for hospital care, physician services, pharmaceuticals, and other health services as other industrialized countries. Pharmaceuticals are only one

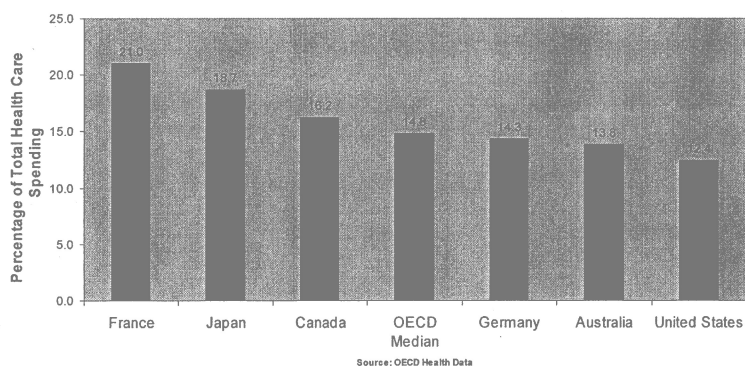
area where the U.S. is in outlier in terms of prices. However, since the focus of this hearing is pharmaceuticals, I will concentrate my comments there.

Other Countries Efforts To Control Pharmaceutical Spending

As part of the Commonwealth Fund grant I have the opportunity to meet with the health ministers from the U.S., Canada, Australia, New Zealand, and the United Kingdom every October for two days in Washington, DC. As part of this meeting, I have learned how much effort these other countries place on controlling pharmaceutical spending. These countries have been operating programs to reduce pharmaceutical prices and determine appropriate utilization for over 20 years. I have also learned that the health ministers spend considerable political capital keeping their programs working.

One reason for their considerable attention to pharmaceuticals is that these countries spend a higher percentage of their healthcare resources on pharmaceuticals than the U.S. (Exhibit 1). As a result, pharmaceutical spending in these countries commands greater policy attention. It is for this reason that these countries have developed a wide range of programs designed to control both pharmaceutical utilization and prices.

Exhibit 1. Percentage of Total Health Care Spending on Pharmaceuticals in 2001



The programs in these countries have adopted a number of strategies to monitor pharmaceutical utilization and prices. Some of the programs determine what drugs are therapeutically equivalent and then pay the lowest price of all equivalent drugs. Some compare the prices paid for the same pharmaceuticals in other countries. Other programs regulate profits or provide an explicit allowance for research and development.

This is in contrast with the U.S. which has no national strategy for determining appropriate utilization, comparing prices to what other countries pay,

setting a reasonable research and development level, or reasonable profit level. Because of this it is not surprising that the U.S. pays considerably more for pharmaceuticals. Because we have done little, it seems unfair to ask other countries to dismantle their programs.

I will now briefly summarize the ongoing programs in Canada, the United Kingdom, Australia, and France.

Canada. In Canada, pharmaceutical prices are controlled through policies at both the federal and provincial level. At the federal level, price controls are negotiated between pharmaceutical manufacturers and the Patented Medicines Prices Review Board (PMPRB), an independent quasi-judicial body. The PMPRB's five members are appointed by the government; the five current members include a neurosurgeon, an accountant, a lawyer, and two economists.

The criteria used by the PMPRB are the price of the same drug in other countries (specifically, the median price in France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States) and the Canadian prices of other drugs in the same therapeutic class. After the initial price of a drug is determined, subsequent price increases are limited to 1.5 times the forecast change in the annual Consumer Price Index.

Pharmaceutical companies are required to report the prices of their patented products to the PMPRB upon release and every six months thereafter. Products that appear to be priced excessively high are subject to an investigation, which is terminated by either (a) determination that the product is priced within guidelines; (b) voluntary compliance by the manufacturer to lower the price; or (c) a public hearing to determine the acceptable price. All drugs under review, including new products and those undergoing an investigation, are listed on the PMPRB's web site and in their annual report for transparency. Of the 1027 patented drugs in Canada in 2002, 875 were within guidelines, 82 were still under initial review, 67 were under investigation, and 3 (all related to Nicoderm) were in public hearings.

While the PMPRB determines the maximum prices paid for drugs in Canada, provinces also administer their own policies. All but one province use a formulary to determine which drugs are available for public reimbursement. Two provinces, British Columbia and New Brunswick, use reference pricing systems which limit reimbursement for drugs to the lowest price of any drug in a particular therapeutic class. Under these reference pricing systems, the provincial governments will only reimburse patients for the price of the lowest-price drug in each therapeutic class. If patients choose to purchase a more expensive drug, they must pay the difference out-of-pocket.

United Kingdom. The United Kingdom does not set the prices of individual drugs, but instead the National Health Service (NHS) controls allowable profit margins in the pharmaceutical industry. The profit margin is set through

agreements that, while voluntary, have been made with every pharmaceutical manufacturer. The allowable profit margin with each company is based mainly on the level of research and development and other domestic investment and the level of long-term risk. The negotiations are confidential but are limited to the range of 17-21 percent rate of return on capital. They are based on confidential financial reports that allow calculation of total sales to the NHS and research and development investment. Companies that earn profits above or below the agreed levels must adjust their prices or reimburse the NHS. Within these profit controls, pharmaceutical companies have freedom in pricing new products. After the initial price is set, subsequent price increases must be approved by the NHS, except for new drug presentations or formulations.

The terms of these agreements are negotiated every five years between the NHS and the Association of the British Pharmaceutical Industry. As part of this agreement, the government may institute direct price controls as well as the profit controls.

Several other policies influence drug spending in the United Kingdom. The NHS maintains a "negative list" of drugs that are not eligible for reimbursement.

These are drugs with limited clinical efficacy. The National Institute for Clinical Excellence also furnishes providers with guidance on the cost-effectiveness of treatments, which can influence provider behavior. These recommendations are made by an Appraisal Committee, appointed by the government and comprising physicians, other health professionals, the NHS, economists, and industry representative. Each guideline is based on reviews of existing evidence by an independent, commissioned group of experts. For transparency, many aspects of the review, including selection of the topic, evidence review, and guideline, are published on the Web. Each review also includes stakeholder consultations.

Finally, all drug spending is capped by global budgets to physician organizations (Primary Care Groups). Every citizen is enrolled in one of these Primary Care Groups. The physicians are required to manage their pharmaceutical budgets to provide drugs for their enrolled population.

Australia. Prices for drugs that are reimbursed under Australia's Pharmaceutical Benefits Scheme are controlled by the Pharmaceutical Benefits Advisory Committee. The Committee is an independent statutory body established in 1954 with appointed members including physicians, economists, pharmacists, and an industry and consumer nominee. The criteria used for setting prices includes (1) the cost-effectiveness of the drug; (2) comparative Australian prices of drugs in the same therapeutic class; (3) prices of the drug in other countries; (4) projected prescription volume of the drug; (5) research and development investment in Australia by the manufacturer (high investment can lead to financial incentives).

Australia was the first country to include cost-effectiveness analysis in its pricing decisions. Advice on the cost-effectiveness evidence supporting each candidate drug is provided to the Committee by the Economics Sub-Committee, consisting of physicians and economists. The transparency of these pricing decisions will be increased, partly as a result of the recent trade agreement between Australia and the United States. The new transparency measures include public release of the outcomes of each drug review, reasons why drugs are included for reimbursement or not, and a review mechanism for decisions.

France. In France, pharmaceutical prices are negotiated between the government and drug manufacturers. The criteria used are (a) the therapeutic benefit of the drug, judged in relation to existing products by an expert group, the *Commission de Transparence* (Transparency Commission); (b) prices of other drugs in the same therapeutic class; and (c) the expected sales volume of the drug. The Transparency Commission comprises 18 government-appointed members, including representatives of the government, physicians, pharmacists, insurers, pharmaceutical companies, and clinical and economic experts. They advise the *Comité Economique du Médicament* (CEM) on the therapeutic value of drugs. The CEM also considers prices of the similar drugs in other European countries, although these are not formally used in pricing decisions (French drug prices are generally lower than in other European countries).

Drug sales are monitored periodically by the government and if volume and expenditures are higher than expected, the drug companies are required to lower their prices or have the drug removed from the reimbursable drug formulary. The CEM plans to increasingly use cost-effectiveness evidence to guide its pricing decisions. In addition to prices, the French government also regulates many other aspects of pharmaceutical sales, including wholesale and retail markups and marketing expenditure by pharmaceutical companies.

In talking with the health ministers and reading the academic literature, there appears to be evidence that the programs in these countries are effectively controlling pharmaceutical prices and promoting appropriate utilization. Access to pharmaceuticals is not a political issue in these countries.

Our own research supports this conclusion. In the *Health Affairs* article that is attached, we compared the levels and the rates of increase in pharmaceutical spending from 1990 to 2000 for the 30 industrialized countries that are members of the Organization for Economic Cooperation and Development (OECD). Exhibit 2 (reproduced from *Health Affairs*) shows that the U.S. spent the most per capita on pharmaceuticals of all 30 OECD countries and twice as much per capita on pharmaceuticals as the median than any other (OECD) country (\$556 versus \$262) in 2000. The U.S. rate of increase in per capita spending on pharmaceuticals from 1990 to 2000 was 6.0%. Only Sweden, Norway, and Australia had more rapid increases during this period and in spite of this more rapid growth all three countries spent half as much as the U.S. on pharmaceuticals per capita in 2000. These three countries were simply catching up to international norms during the 1990s.

Exhibit 2. Pharmaceutical Spending in OECD Countries

	Spending on pharmaceuticals in 2000		Average Annual Growth in Pharmaceutical Spending per Capita
	percent of GDP	per capita spending (\$PPP)	
Australia	1.0	252	6.9%
Austria	-	-	-
Belgium	1.4	352	4.1%*
Canada	1.4	385	4.8%
Czech Republic	1.8	260	5.8%
Denmark	0.8	223	3.9%
Finland	1	259	5.2%
France	1.9	473	4.2%
Germany	1.4	375	1.7%
Greece	1.5	258	5.2%
Hungary	1.8	193	-0.1%
Iceland	1.3	382	2.3%
Ireland	0.6	187	4.9%
Italy	1.8	459	2.1%
Japan	1.2	314	0.6%
Korea	0.8	110	-0.4%
Luxembourg	0.7	317	1.4%
Mexico	1.1	93	-
Netherlands	1.0	264	4.5%
New Zealand	1.1	210	3.0%
Norway	0.7	217	7.4%
Poland	-	-	-
Portugal	2	334	5.7%
Slovakia	-	-	-
Spain	1.4	264	4.8%
Sweden	1.0	244	6.8%
Switzerland	1.1	345	3.0%
Turkey	-	-	-
United Kingdom	1.1	253	6.0%
United States	1.6	556	6.0%
Median	1.2	262	4.5%

Source: Health Affairs

Politicians in these countries utilize considerable political capital to create and maintain these programs. Because of the apparent success of these programs and the political capital already invested, it would be a difficult negotiation for the U.S. trade representative to require other countries to make significant policy changes. They have developed criterion which justifies the prices they are setting. This is not something the U.S. has done.

Perhaps the U.S. should try some of these programs instead of asking other countries to dismantle their programs.

The next question is whether it is even necessary. Are pharmaceutical prices really higher in the U.S.?

Price Comparisons

There is some disagreement among experts regarding how much more (if any) Americans pay for pharmaceuticals. Patricia Danzon and Michael

Furukawa wrote an article in *Health Affairs* last winter that compared the prices U.S. consumers pay for pharmaceuticals to prices in other countries. They found rather small differences between what the U.S. pays and what other countries pay. The abstract of their article is presented below.

“This study compares average price levels for pharmaceuticals in eight countries- Canada, Chile, France, Germany, Italy, Japan, Mexico, and the United Kingdom- relative to the United States. Our most comprehensive indexes, adjusted for U.S. manufacturer discounts, show Japan’s prices to be higher than U.S. prices. The decline of the Canadian dollar and rise of the U.K. pound contribute to the finding of lower Canadian prices and higher U.K. prices in 1999 than in 1992. Our findings suggest that U.S. - foreign price differentials are roughly in line with income and smaller for drugs than for other medical services. “

My colleagues and I took a similar approach using the same data set but updated the numbers to the first three quarters of 2003 and reached a very different conclusion. Data on the prices of pharmaceuticals in Canada, France, the United Kingdom, and the United States for January to September 2003 were obtained from IMS Health. These data have been used in several previous international comparisons of pharmaceutical prices including the Danzon and Furukawa study. These four countries were chosen because they are similar in terms of economic development.

We compared the prices of a basket of the 30 pharmaceutical products with the highest total spending (including both branded and generic drugs) in the United States that are also sold in the other countries. Each of the 30 items used to construct the index represents a specific manufacturer, compound, and form (e.g., tablet). For example, the top-selling pharmaceutical product in the U.S. was Lipitor, manufactured by Pfizer in tablet form. The price of a 10-mg. tablet of Lipitor was \$1.81 in the United States, \$0.99 in Canada, \$0.67 in France, and \$0.90 in the United Kingdom in 2003. Prices were adjusted from each country’s currency units to U.S. dollars using January 1, 2003 exchange rates.

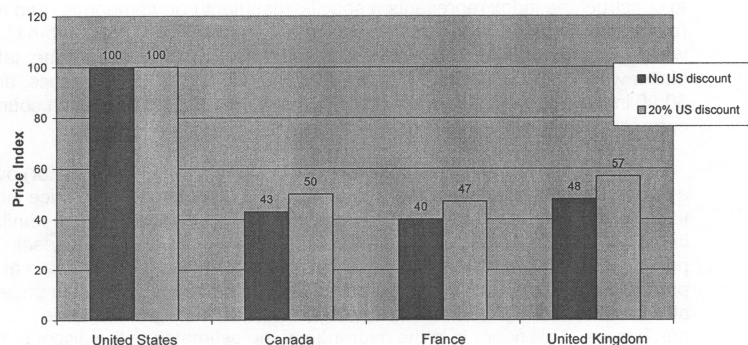
We first averaged the prices for each specific product (e.g. Lipitor) over all available dosage strengths for each country. We then calculated a price index by taking a weighted average of the prices of these 30 products, using the units sold in the U.S. as the weight. The prices compared are the average wholesale prices – those faced by major U.S. purchasers, not individual consumers at pharmacies. Since U.S. purchasers rarely pay the average wholesale price, we also calculated the price index assuming a 20% discount given to large purchasers. This figure is in the midrange of the estimates of the discount that the private insurers administering the Medicare drug benefit will be able to negotiate with pharmaceutical companies.

These methods differ slightly from those used in the comparison by Danzon and Furukawa. The construction of any price index involves a tradeoff

between the representativeness of the basket of good used and the standardization of the market basket across countries. Danzon and Furukawa opted for greater representativeness, while we opted for greater standardization. Danzon and Furukawa used the “molecule-indication” as the unit of analysis, which averages the prices for each pharmaceutical compound over the various available dosage strengths and forms. Since countries have different prescribing patterns for different dosages and forms of the same compounds, this methodology leads to a more comprehensive index – the units comprising the index are more representative of the prescribing patterns in each country. However, since the index averages different dosages and forms, it is not standardized as closely as our methodology. We opted for greater standardization so that we could simulate the prices that would be paid in the U.S. for the most-commonly used products if U.S. utilization were fixed but prices were the same as those in other countries. Danzon and Furukawa addressed a different question, comparing prices broadly across the entire market and testing the effects of income, exchange rates, and other factors on these differences.

The results of the price comparison are shown in Exhibit 3. Prices for the basket of pharmaceutical prices in the U.S. are given a value of 100. Averaged over the market basket of 30 pharmaceutical products, prices were 57% lower in Canada, 60% lower in France, and 52% lower in the United Kingdom compared to the United States. Assuming a 20% discount for U.S. purchasers, prices were 46% lower in Canada, 50% lower in France, and 40% lower in the United Kingdom compared to the United States.

Exhibit 3. Relative Prices of Thirty Pharmaceuticals in Four Countries, 2003



These price differences are greater than those reported by Danzon and Furukawa. One reason is the methodological differences described above. However, the more important difference may be our use of more recent data

(2003 vs. 1999). Pharmaceutical prices in the U.S. have risen much more rapidly in the 1999 to 2003 period compared to other countries.

Knowing the relative price of pharmaceuticals in the U.S. compared to other countries is critical for good public policy. If Danzon and Furukawa are correct and there is minimal difference between what the U.S. pays and what other countries pay for pharmaceuticals, then what is the reason for the U.S. trade representative to argue that the other countries should raise their prices.

However, if our numbers are correct, then a strategy for equalizing drug prices is worth considering. Because of the difference in the findings among experts in the extent of the price differential, this is an issue the GAO should investigate further.

Assuming that the U.S. trade representative believes our numbers and concludes there are large differences between what the U.S. pays and what other countries pay, the question becomes what action to take. One suggested approach is to have the U.S. trade representative argue for higher pharmaceutical prices in other countries.

International Price Fixing

One approach is for the U.S. trade representative to negotiate with other countries to raise their pharmaceutical prices in order to equalize the support for research and development internationally. The argument is that all industrialized countries should share equally in the research and development costs. In order to implement this approach, the U.S. trade representative would need to have a target price for each drug and encourage each country to pay this target price.

I am uncertain what standard should be used to negotiate pharmaceutical prices on an international scale. Two metrics commonly used in other countries to set pharmaceutical prices are: (1) a desired level of research and development or (2) a desired profit margin.

As part of their political process, other countries appear to have decided on significantly lower levels of pharmaceutical research and development and/or profit. As part of a trade negotiation, would the U.S. be willing to accept a lower level of research and development or a lower level of profits if an international standard were adopted? I doubt it. I also doubt the other countries would accept the U.S. level.

In any case the trade negotiation approach strikes me as price fixing on an international scale with pharmaceutical profits and research and development determined by trade negotiation. Trade negotiations would need a standard and that that standard would become the international price.

Free Market Approach

Another approach is the free market.

This is the approach that some have advocated for the U.S. to take. A free market approach works best for certain goods and services. Economic theory provides some guidance when a free market approach works best. One situation where a free-market approach does not work is when there are multiple purchasers and only one seller. This is known as a monopoly.

Pharmaceutical companies are given patents on brand name drugs. These patents do not allow other firms to manufacture drugs with similar chemical compounds. There are legitimate reasons for pharmaceutical companies to receive patents, perhaps the most important is the fostering of research and development. Pharmaceutical companies would not invest in research and development if their competitors could immediately gain access to the clinical compounds and begin mass production. The cost in producing pharmaceuticals is mostly in the research and development and not in the manufacture.

Because of patent protection, it is misleading to state that brand name drugs in the U.S. are purchased in a free market environment. The situation is one of a single manufacturer of brand name pharmaceuticals selling to diverse purchasers. Patents have created individual monopolies for name brand drugs.

Generic drugs are different. There is competition for generic drugs because other manufacturers can compete on the basis of price and quality. It is not surprising, therefore, that generic drugs are often less expensive in the U.S. than other countries. Competition brings down prices in the proper circumstances.

Economic theory tells us that prices will be high in the situation where there is only one supplier because the manufacturer has no incentive to lower prices. It is a classic example of market failure. The manufacturer has no economic incentive to lower prices even if prices are raised in other markets. Economic theory suggests that even if the U.S. trade representative were able to negotiate lower prices in other countries that pharmaceutical companies would maintain their prices in the U.S. for brand name drugs. They will set the price in the U.S. which maximizes their profits.

There are numerous ways to minimize market failure in this case. One possibility is to remove all patents. This, however, would also eliminate nearly all pharmaceutical research and development.

A second option is to create two monopolies- a monopoly supplier (the pharmaceutical company) and a monopoly purchaser (the government). This is effectively what other countries are doing. Economic theory cannot predict the final negotiated price in this situation. Empirical data from other countries,

however, gives a good indication. Pharmaceutical prices are twice as high on average in the U.S. compared to these other countries.

The U.S. may want to pursue a free market approach in spite of economic theory. The free market may be able to determine a reasonable price. We have a way of determining how much extra we are paying with the free market system. We can compare the prices we are paying in the U.S. to prices in other countries. The prices paid in the other countries form a reasonable benchmark for the U.S.

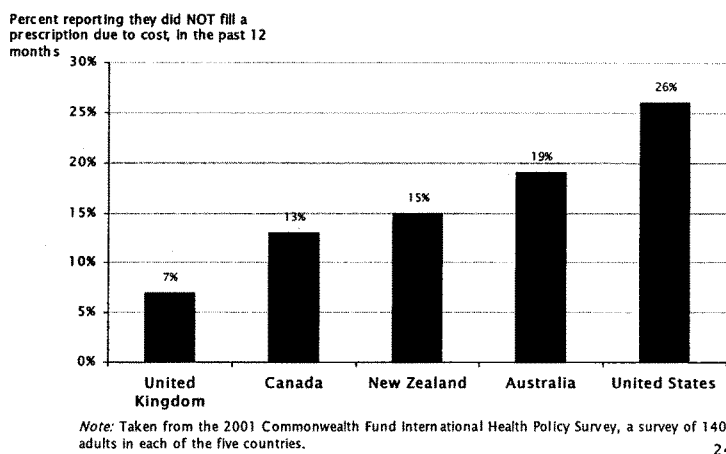
Opportunity Costs

Does it matter that the U.S. pays higher prices for pharmaceuticals? A fundamental tenet of economics is opportunity costs. There are alternative uses for available resources. When we pay higher prices for pharmaceuticals we get more pharmaceutical research and development which is good. However, there are tradeoffs.

Currently, the U.S. has a choice. One opportunity is to continue to pay high prices for pharmaceuticals and get more research and development. A second option is to pay lower prices and improve access to pharmaceuticals.

I have attached a chart which shows the result of a survey conducted by the Commonwealth Fund in 2001 (Exhibit 4). A nationally representative sample of the adults in the United Kingdom, Canada, New Zealand, Australia and the United States were asked if they did not fill a prescription due to cost in the past 12 months. The survey results show that U.S. citizens are most likely to not fill a prescription because of cost. Higher prices reduce access to pharmaceuticals.

Exhibit 4. Financial Barriers To Pharmaceuticals



“Doughnut Holes” and Price Controls

Access to pharmaceuticals could be a problem in the recently enacted Medicare Modernization Act because of the “doughnut hole”. Lower prices for pharmaceuticals could allow the Medicare program to eliminate the “doughnut hole” in the Medicare drug benefit. This is a clear choice for the Congress.

In order to determine how much lower pharmaceutical prices would have to be in order to eliminate the “doughnut hole”, we developed a microeconomic simulation of the effects of Medicare Part D on Medicare beneficiary behavior. The model uses data from the 1999 Medicare Current Beneficiary Survey (MCBS) to simulate a scenario for 2006 by adjusting income, population weights, and drug spending based on data from the Medicare Trustees' Reports, Census Bureau and National Health Accounts. The model simulates the choices made by Medicare beneficiaries as they evaluate their options. The choice is based upon whether the new plan offers net benefits to the beneficiary in the form of reduced premiums, reduced out-of-pocket drug costs, or greater protection from risk compared to their existing coverage. Once an individual chooses a plan, the effects on spending are estimated based upon an assumed spending elasticity of $-.3$, with adjustments for the effects of deductibles, “doughnut holes”, and stop-loss protection.

The model was run using an alternative assumption about prices for prescription drugs to see how much lower prices would need to be in order to

eliminate of the "doughnut hole". The original Medicare plan was simulated with a coinsurance rate of 25%, deductible of \$250, and a doughnut hole beginning at \$2,250 and ending at \$5,100 with 5% coinsurance after that point. A premium subsidy of 74.5% was assumed for all Medicare beneficiaries. Deductibles, coinsurance and premium subsidies were adjusted for low-income beneficiaries to match as closely as possible the features of the bill passed. An alternative benefit was then modeled with the doughnut hole eliminated and assuming a 50 percent price discount. This price reduction is what other industrialized countries have been able to achieve.

Overall Effects

Exhibit 5 shows the overall effects of the simulations on total spending and the distribution of spending among payers (Medicare, out-of-pocket costs, and other third-party payers). The model indicates that total spending on pharmaceuticals by Medicare beneficiaries in 2006 will be \$101.9 billion, \$44.5 billion of which will be financed by the Medicare program.

Exhibit 5. Spending on Medicare Prescription Drug Benefits in 2006						
Model Version	Model Assumptions		Drug Spending by Medicare Beneficiaries in 2006 (Billions of Dollars)			
	Stop-Loss Level	Price Discount	Total Drug Spending (Billions)	Medicare	Out Of Pocket	Third Party Payers
A. Current legislation	\$5,100	20%	\$101.90	\$44.50	\$31.00	\$26.40
B. Alternative benefit	\$2,250	50%	\$67.70	\$46.20	\$15.00	\$6.50

Under our alternative scenario, pharmaceutical prices were reduced 50 percent and the doughnut hole was closed. Under this model the total spending in 2006 would be \$67.7 billion. Medicare spending would remain nearly unchanged in 2006, at \$46.2 billion. In other words, in the scenario of 50 percent lower prices and "no doughnut hole" Medicare spending would be equivalent to Medicare spending in the current legislation. The major spending reductions would be in out-of-pocket spending and other spending.

Our microsimulation model is for 2006 only. Using estimated growth in per capita drug spending from the National Health Accounts and estimated growth in the Medicare population from the Medicare Trustees' Reports, we estimate that total Medicare drug spending during the period from 2006 to 2013 would equal \$667 billion for the current legislation. This is higher than the projections of the Congressional Budget Office (\$408 billion) and the Administration (\$534 billion). Our out-year projections for Medicare spending for the period from 2006 to 2013 would decline to \$551 billion under the scenario of

lower pharmaceutical prices. The Congressional Budget Office and the Administration have incorporated assumptions about beneficiary behavior that are more complex than our simple extrapolation of the Medicare actuaries' spending and population projections. This could explain their lower estimates in the out years.

There are opportunity costs to higher pharmaceutical prices. Congress has a real choice - higher pharmaceutical prices and more research and development or elimination of the doughnut hole in the Medicare program. The choice could be between doughnut holes and price controls.

Thank you Mr. Chairman, and members of the Committee for this opportunity to testify this morning. I would be happy to answer any questions.

Response to question from Senator Kyl

The Organization for Economic Cooperation and Development (OECD) reports data on pharmaceutical industry research and development (R&D). The OECD is a group of 30 industrialized democratic countries. The OECD includes many of the countries in the European Union (EU), but not all. There are also some countries in the OECD that are not members of the EU, such as Australia, Canada, and Japan.

The table below shows pharmaceutical R&D spending per capita and total pharmaceutical R&D spending. The United States spends slightly more per capita on pharmaceutical R&D than the other 15 countries which report data to the OECD (\$45 compared to \$39).

Sweden, Denmark, the United Kingdom, and Belgium spend more per capita on pharmaceutical R&D than the United States. These countries, which all use some form of price controls for pharmaceuticals, are able to maintain R&D investment in their countries at higher levels than the United States.

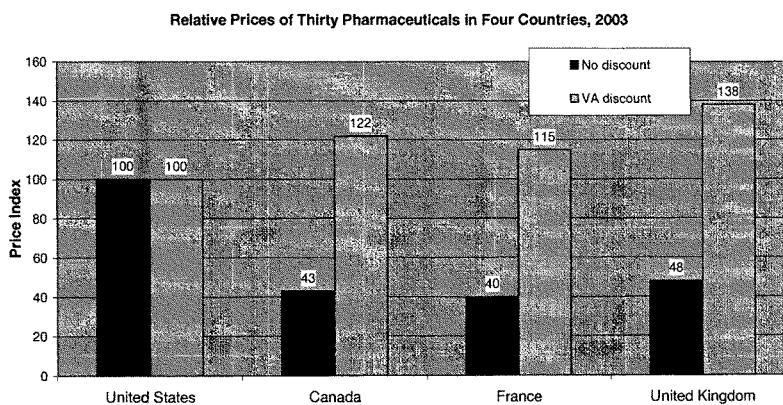
Pharmaceutical R&D Spending in OECD Countries in 2000		
	Pharmaceutical R&D Spending Per Capita (\$PPP)	Pharmaceutical R&D Spending (Millions \$PPP)
Sweden	109	974
Denmark	90	480
United Kingdom	74	4,378
Belgium	66	684
France	43	2,534
Japan	38	4,797
Finland	30	157
Netherlands	29	471
Germany	28	2,298
Ireland	23	89
Canada	18	550
Australia	13	248
Italy	11	635
Norway	11	49
Spain	8	307
United States	45	12,945
All Others (Average)	39	18,651

Source: OECD Health Data 2003

PPP is purchasing power parities, an adjustment for cost-of-living differences.

Response to questions from Senator Lincoln to Dr. Anderson

1. Yes, the new Medicare drug law weakens Medicare's bargaining position by prohibiting direct negotiations over pharmaceutical prices with the pharmaceutical industry. If this prohibition was not included, it is possible that Medicare could pay drug prices similar or lower than those paid in other countries because of its larger volume.
2. The figure below shows the result of a study conducted by myself and several colleagues on drug prices. It shows that average wholesale drug prices in other countries are approximately less than half those paid in the United States. The orange bars show prices in other countries relative to the United States assuming that purchasers could receive a 65% discount from average wholesale prices. The Veterans' Administration achieves discounts that are as high as 65% off average wholesale prices.¹ With these discounts drug prices in the United States are 22% lower than in Canada, 15% lower than in France, and 38% lower than in the United Kingdom.



3. Australians and Americans are very similar in how worried they are about access to advanced medical care, including pharmaceuticals, according to a 1998 survey.² The survey showed that 19% of Australians and 21% of Americans were "very worried" about access to the "most advanced medical care, including medicines, tests, or treatment". The survey also found that 52% of Australians

¹ Oehson W, "Pharmaceutical Discounts Under Federal Law: State Program Opportunities," Public Health Institute report, May 2001, available at http://www.ppsv.com/issues/pharm_discounts.pdf.

² Donelan K, Blendon R, Schoen C, Davis K, and Binns K, "The Cost of Health System Change: Public Discontent in Five Nations," *Health Affairs* 1999, 18(3): 206-216.

and 53% of Americans were “not too worried.” I don’t have any information about how Australians view their national formulary in particular.

4. The Australian reference pricing system evaluates each new drug for its clinical benefits and cost-effectiveness. A higher payment is added to the price of drugs that have a demonstrated clinical or cost-effectiveness advantage over others.
5. The doughnut hole could be eliminated from the Medicare drug benefit with a 50% price discount without changing the level of spending.



Committee On Finance

Max Baucus, Ranking Member

NEWS RELEASE

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For Immediate Release
Tuesday, April 27, 2004

Contact: Laura Hayes
202-224-4515

**Statement of Senator Max Baucus
Hearing on International Trade and Pharmaceuticals**

Thank you, Senators Kyl and Thomas, for holding this joint subcommittee hearing. Finance subcommittees don't hold hearings very often. That ought to change. In particular, I welcome more hearings on drug pricing policy. This is an extremely important issue. And it will become even more important once the Medicare drug benefit is implemented.

Medicare beneficiaries and other consumers tell me drug prices are rising twice the rate of inflation. And they tell me the government should not stand in the way when Americans want to import cheaper drugs from Canada or Europe.

Employers, health plans, and insurers tell me the cost of prescription drugs is one of the fastest growing components of health care costs in the United States. And they tell me rising health costs are affecting the ability of U.S. companies to compete internationally. We need to address these issues or risk the consequences to the long-term health and competitiveness of the U.S. economy. And U.S. pharmaceutical manufacturers tell me other countries have imposed restrictive pricing measures on their products. They tell me these price controls are unfair, anticompetitive, and a root cause of higher prices in the U.S.

So clearly we have work to do. We need to learn more about the mechanisms other countries use to determine drug prices. We also need to learn more about how prices are determined by payers here in the U.S. And, frankly, we should also devote more resources and attention to comparative drug effectiveness studies. The U.S. is clearly behind on that front.

No single answer exists to high and rising drug prices. Some claim that other countries use pricing mechanisms that are too restrictive, that lack transparency, and that artificially hold down prices through government strong-arming tactics. But leaving drug pricing entirely to drug manufacturers may not be the best idea either. The market has not contained prices that private plans and employers pay for drugs here in the U.S.

And it is my understanding that some countries actually have more – not less – transparency in the way that coverage and pricing decisions are made than we do in the U.S. Transparency means there is an open, public process for determining which drugs are covered, at what price, and why. In the end, we must find a balance between patient access and fair pricing mechanisms. The U.S. government may have something to learn from other nations in this regard.

A balanced pricing policy must take into account the ability of consumers to get the drugs they need. We must consider U.S. trade policy and the interests of U.S. companies abroad. And

with regard to Medicare and other public programs, we must also consider the interests of the taxpayers. So this hearing is a good opportunity to explore these issues further. What are other countries doing? What can we learn from them? What can they learn from us?

And just a few words about reimportation: I am encouraged by new efforts to address head-on the safety concerns about imported pharmaceutical products. Safety has been the main roadblock to moving forward on reimportation. Chairman Grassley's bill and the bipartisan bill introduced last week provide thoughtful approaches to safety concerns that seem like reasonable policy to me. I may have differences with specific provisions in the bills, but they are a good starting point to moving forward.

I would add, however, that reimportation strikes me as a short-term fix and not a long-term solution to the higher drug prices that Americans pay. I am concerned that reimportation may encourage further movement of jobs outside of the United States. If U.S. drug companies begin selling more drugs from Canada, they might start producing more drugs in Canada. And U.S jobs may move to Canada as a result. And I am concerned that American drug manufacturers may react to reimportation in ways that harm other countries – and ultimately, American consumers.

If a large share of the American drug-buying market starts buying lower-priced drugs from Canada, American manufacturers may cut back the amount of drugs that they supply to Canada. Canadians may not get the drugs that they need. And ultimately, Canada may react by restricting the ability of Americans to reimport drugs from Canada. We need to start thinking about the long-term implications of reimportation and potential solutions to address those problems before they even arise. Thank you and I look forward to hearing from our witnesses.

John E. Calfee, Ph.D.

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Written testimony

Before the

United States Senate Committee on Finance

Joint Committee on International Trade and Health

In Public Hearings on

International Pharmaceutical Prices

Tuesday, April 27, 2004

I wish to thank the Joint Committee on International Trade and Health for inviting me to testify today in today's hearings on international pharmaceutical prices. I am a Resident Scholar at the American Enterprise Institute for Public Policy Research, where I have conducted research on pharmaceutical markets and other topics. The views I present today are my own and do not necessarily represent those of the American Enterprise Institute.

My testimony focuses on five points.

1. Economically advanced nations other than the United States control the prices of innovative pharmaceuticals at below-market levels

All advanced economies but the United States control the prices of innovative drugs.¹ Price control regimes take on a variety of forms including profit limits, cost-effectiveness-based ceilings, reference pricing (where prices or reimbursement for all drugs in a therapeutic class are set equal to that for the cheapest drug within the class), adopting price ceilings in other nations, and directly negotiated ceilings.

A natural question is the extent to which foreign controls hold prices below market levels. By “market” levels, I refer to prices at which drugs would be sold to non-government buyers in the absence of controls. What would those prices be? A starting point is prices at which drugs are sold in the U.S. to buyers other than government. The American non-government prescription drug market amounts to about \$126 billion annually (excluding drugs covered by Medicaid, the Veterans Administration, Medicare’s limited Part B program, and other much smaller programs). That is far larger than the

¹ A convenient source comparing drug prices in wealthy nations is Canada’s Patented Medicine Prices Review Board (PMPRB), which regularly publishes an index that invariably shows American prices to be substantially higher than those in Canada and other nations. This is available at www.pmprb.com/CMFiles/ar2002e21LEF-6252003-6142.pdf. Danzon and Furukawa 2003 described the many difficulties in constructing accurate and unbiased international drug price comparisons (because of differences in generic status, dosage, therapeutic category, currency fluctuations, and other factors), thus casting doubt on the precision of the PMPRB’s indices. But the basic points -- that Canada and western European prices are substantially higher than American prices, and that this is very much by design -- remain largely true. In addition to the article cited above, Danzon and her coauthors have written a series of papers on foreign price controls and their effects, while emphasizing the difficulty of constructing simple measures of the effects of price controls. See Danzon 1997, Danzon and Chao 2000, Danzon and Ketcham 2003, and Danzon, Wang, and Wang 2002. An indispensable source on the variety of foreign price control regimes is a series of papers written or organized by Panos Kanavos at the London School of Economics. These are available at <http://pharmacos.eudra.org/F3/g10/p6.htm>.

entire pharmaceutical market in any single European nation (Germany's being the largest at \$20 billion) or the entire Japanese market, the second largest in the world at \$53 billion.² In the huge non-government American market, prices are determined primarily through competitive forces. These forces do not yield a single "market price," as transaction prices depend partly on negotiations between pharmaceutical manufacturers and large buyers (especially the pharmaceutical benefit managers, or PBMs).³

Foreign prices would probably be lower than American prices even if they were not controlled by governments. Economists have often noted that it is in the financial interest of pharmaceutical manufacturers to charge lower prices to less wealthy nations (Danzon 2001; Danzon and Furukawa 2003; Danzon and Towse 2003; Wagner and McCarthy 2004). In the past decade or so, per capita incomes in the U.S. have come to exceed those in Canada, Western Europe, and Australasia by some 25 to 40 percent (OECD data). Such disparities would be expected to generate lower pharmaceutical prices abroad even in the absence of controls. The same logic can apply to other products. For example, a controversy arose in 1999 over the fact that Canadian automobile prices were some 16 percent lower than U.S. prices (Graham 2003)

Foreign price controls are explicitly designed to reduce prices below the levels that would arise from natural economic forces. This is clear from the statements of price control boards such as Canada's Patented Medicine Prices Review Board (PMPRB). However, the extent to which controlled prices fall below free-market levels is not easily assessed. Danzon and Furukawa (2003) calculated that in 1999, average price disparities between U.S. and Western Europe for branded drugs were roughly in line with relative per capita GDP, while U.S.-Canada price disparities were roughly twice the disparity in per capita GDP. Price disparities are larger for some individual drugs, of course, and

² U.S. data are from CMS National Health Accounts. German and Japanese data are from the *IMS World Review*.

³ A useful review of the economics of differential pricing in U.S. markets is Frank 2001.

they may have increased on average since 1999 despite the recent weakness of the U.S. dollar. Germany and other nations often resort to ad hoc price reductions in addition to whatever ceilings would normally prevail.⁴ There seems little doubt that for many of the most important patented drugs, international price disparities are often substantially larger than can be accounted for purely in terms of income differences.

The situation is quite different for off-patent drugs, i.e., generics. Danzon and Furukawa (2003) found that generic drug prices in the U.S. tended to be lower—and often much lower—than those in Western Europe. As will be noted below, this raises the possibility that European nations have available to them a tool for providing more reasonable rewards for innovative drugs while reducing costs in the generic sector.

A relatively little noticed fact in the debate over pharmaceutical prices is that within the U.S., spot checks and informal surveys reveal substantial disparities in retail prices, apparently due to large differences in retailer cost structures, competitive conditions, and markups. For example, thirty tablets of the antibiotic Amoxicillin can cost as little as \$4 and as much as \$27.95 in the same metropolitan area.⁵ In a recent presentation at a Canadian conference of cross-border pharmaceutical trade, Palmer (2004) presented data indicating large differences in retail prices within both the U.S. and Canada.

2. In nations with price controls, patients have faced delays in the introduction and uptake of innovative new drugs

Nations with pharmaceutical price controls usually employ a two-part approval process: first, medical approval (roughly equivalent to FDA approval of new drugs in the U.S.), followed by “registration” of negotiated prices and reimbursement. A substantial and growing body of evidence documents delays in both the approval of innovative drugs and the registration of reimbursement or wholesale prices in nations with the most

⁴ See Kanavos ____, and ____

⁵ Graham 2003; *Consumer Checkbook*.

stringent price controls. In some cases, the delay can involve several years or even the failure to introduce certain pharmaceuticals at all. In their analysis of the fate of 85 new chemical entities in 25 countries, Danzon, Wang, and Wang (2002) found (p.18), “The three countries that do not require price approval before launch had the most launches: the US led with 73 launches, followed by Germany (n=66) and the UK (n=64). At the other extreme, only 13 NCEs were launched in Japan, followed by Portugal (n=26) and New Zealand (n=28).” They concluded (p. 3), “Our results suggest that countries with lower expected prices or smaller expected market size experience longer delays in access to new drugs, even after controlling for per capita income and other country and firm characteristics.”

A December 2002 report from Cambridge Pharma Consultancy provides more detail. The European Union has established a goal of registering prices for new drugs within either 90 or 180 days after medical approval, depending on the nature of the drug. The Cambridge Pharma report found that most European countries take far longer (p.17): “Patients in Belgium on average wait 2 years longer to receive new medicines than patients in the UK and Germany. Although the average delays are lower in other countries, patients could still wait more than 2 years in Austria, Greece, Finland, France, Italy, and Norway. These delays are usually attributable to extended reimbursement negotiations.”

European nations may also be slower to adopt innovative drugs after they have been approved. Gilbert and Rosenberg (2004, published by the Bain consultancy) noted that of patients for whom the statin class of cholesterol-reducing drugs were recommended, 56 percent of American patients have been prescribed statins versus only 26 percent of the corresponding group of German patients. The authors also noted that cardiac mortality rates had declined more rapidly in the U.S., by 13 percent compared to 8 percent in Germany between 1990 and 2000.

It is difficult to assess the reasons for these delays in approving and using innovative drugs. Clearly, price negotiations take time, but health systems usually have ample advance notice before a new drug actually gets approved. Many drugs are approved in the U.S. before they are approved in Europe, and in any case, most new

drugs are widely discussed in the medical literature and the medical community well before regulatory approval. One reason for delay may simply be a reluctance of the European and Canadian health care systems to take on the burden of paying for new drugs. Because direct-to-consumer advertising is prohibited in these nations, pharmaceutical manufacturers cannot appeal directly to patients while approved drugs await the outcome of pricing negotiations, nor can they use advertising to accelerate uptake among under-treated populations.

3. Pharmaceutical price controls discourage the development of innovative new drugs

The linkage between prices, profits, and pharmaceutical R&D is nearly universally recognized by economists.⁶ They typically emphasize that price controls are bound to blunt R&D incentives. For example, (p.5) “If the manufacturer or investors, anticipating [regulated prices], expect that the prices the various jurisdictions will ultimately set will not in the aggregate cover the cost of development plus a return to capital, the manufacturer will not develop the drug, even though the willingness to pay for the drug in the world might greatly exceed the drug’s development costs.”⁷ An essential problem is that pharmaceutical development involves large sunk costs, lengthy development times, and great financial risk. When the product is finally ready for marketing, its benefits can apply to populations of all nations including those that set price ceilings. Thus price regulators have an incentive to impose relatively low ceilings, confident in the knowledge that manufacturers will still want to sell the product as long as ceilings are well above the costs of manufacture and distribution. Drug developers must take these incentives into account when raising and allocating R&D funds. The

⁶ Useful sources include cf. Scherer 2001; Grabowski and Vernon 2000 as cited in Vernon 2004; Lichtenberg 2001? H.A. 2001; Newhouse 2004; Frank 2001; Danzon 2000 and 2001; and citations therein.

⁷ Newhouse 2004.

clear implication is that the prospect of price controls can substantially undermine incentives to develop new drugs.

Because the benefits of pharmaceutical innovation are essentially global, the progress of R&D depends on the global contribution to pharmaceutical profits, which are the primary source of new drug development (cf. Scherer 2001). To the extent that foreign price controls reduce the overall payoffs from innovation, we can expect an adverse impact on total worldwide pharmaceutical R&D regardless of where that research takes place. Although it is difficult to quantify these effects, several studies indicate that they are significant. Danzon observed in 1997 (p. 63), "There seems to be a rough negative correlation between the stringency of a country's price controls and the innovative success of its domestic pharmaceutical industry." Her 2001 survey of pharmaceutical economics reviews the extant literature as of 1999, which has been extended by her work with several colleagues. These show that price controls tend to reduce the returns to innovative drugs in a variety of sometimes subtle ways. An econometric study by Vernon (2004) finds that for a sample of large pharmaceutical firms, R&D investment was determined partly by the share of the firms' drugs that were sold in nations with relatively stringent price controls. Although the U.S. has been largely free of pharmaceutical price controls, an analysis of the 1993 Clinton Administration health plan, which would have capped the prices of innovative drugs, found that stock prices in the pharmaceutical industry declined when the prospects of passage of the Clinton plan were greatest (Ellison and Mullin 2001). These results are consistent with the fact that the rate of increase in R&D expenditures dropped substantially during 1993 and 1994 (Calfee 2000).

Also relevant is the decisive shift of pharmaceutical R&D activity in the past decade and a half toward the United States as European price controls took effect. In 1990, European pharmaceutical firms outspent American firms in research and development by 8 billion Euros to 5 billion Euros. In 2000, U.S. firms outspent European firms by 24 billion Euros to 17 billion Euros (EFPIA, p. 4). European pharmaceutical firms have also been shifting the locus of their R&D to the U.S. The British firm Glaxo Smith-Kline moved its operational headquarters to the U.S. in 2000.

Novartis, a Swiss firm, moved its research headquarters to Cambridge, Massachusetts. The German firm Schering AG moved its therapeutics division to the U.S. Organon, formerly the only established pharmaceutical R&D firm in the Netherlands, relocated to New Jersey in 2001.

The U.S. share of successful innovation has also increased dramatically. In 1988, American manufacturers developed only 19 of the 50 best-selling drugs worldwide. By 1998, American manufacturers sold 33 of the top 50 drugs. By 2001, American firms were selling 8 of the top 10 drugs worldwide, and one of the remaining two was from a joint venture between Takeda (Japan) and Abbott (U.S.). The pattern for biotechnology drugs is most striking, as U.S. manufacturers account for 14 of the top 15 biotechnology drugs.⁸

These patterns reflect the fact that no objective basis for “fair” or “reasonable” drug prices or profits exists (cf. Calfee 2001). Regulators of pharmaceutical prices cannot base prices on the value of drugs, because that would tend to mimic the very market prices that controls are supposed to correct. Controllers cannot set prices to encourage the “right” research because they lack the necessary information, such as the ultimate value of a particular drug or the likelihood of success of a specific line of research. Finally, basing prices on the actual development costs of individual drugs is neither practical nor appropriate. This is partly because research and administrative expenses are shared among numerous drugs and, sometimes, among several firms, some of whom may have failed to create a marketable drug at all. Regulators also have no objective and consistent way to assess the degree of financial risk that was overcome in the drug development process, including the research failures and bankruptcies that may have preceded the creation of a financially successful new drug. Thus there is simply no way to construct price controls in a manner that assures reasonably efficient incentives for R&D. The lack of a simple, straightforward approach is one reason why international price controls are quite diverse, with several nations simply borrowing price ceilings from other nations.

⁸ Redwood presentation in the Dec. 2003 GMF conference.

European authorities, especially in Germany, have undoubtedly noticed that their automobile industry, which like pharmaceuticals is also research-intensive and rebounded strongly after its total destruction in World War II, has continued to thrive, while its pharmaceutical industry, which once dominated world markets, has fallen behind. Recent European Commission reports have concluded that price controls have harmed the European pharmaceutical industry, and perhaps should be rethought (Echikson 2003). A recent report from Bain Consulting argued that on the whole, the financial costs of the decline in the European pharmaceutical industry may outweigh the financial savings from price controls (Bain 2004).

4. Economically advanced nations are starting to use price controls to free-ride on pharmaceutical R&D paid for by American consumers

As a general rule, the clinical trials that lead to a new drug approval demonstrate the value of that drug not just in the nations where the drug was developed or the trials were conducted, but in almost any comparable population in the world. In other words, research conducted with the American market in mind demonstrates that Australians could benefit from the same drug. This commonality is recognized in the drug approval procedures in Australia and virtually all other advanced nations, where great weight is placed upon the FDA-approved clinical trials used for drug approval in the United States.

These circumstances, combined with the fact that most pharmaceuticals can be manufactured and distributed for a fraction of what they cost to develop, create a temptation for nations to free-ride on research by cutting drug prices. There is some evidence that free-riding has begun to occur. In a September 25, 2003 in Cancun, Mexico, former FDA Commissioner McClellan noted:

“In many ways, the economic consequences of overly strict price controls on drugs are no different than violating the patent directly through compulsory licensing to make copies of the drug. Either way, there isn't likely to be a fair payment based on the value of the new patented product. This year, Americans, who account for a fraction of prescription drug use worldwide, will pay for about half of all pharmaceutical spending worldwide. By contrast, citizens in the world's third largest economy,

Germany, paid less than five percent. The same kind of drug payment disparity is true for many other developed nations who have about as much ability to pay as Americans do.”

The data support McClellan’s observation. In 1990, U.S. revenues accounted for 31 percent of the worldwide market. Canada plus the five largest European nations were almost equal to that, at 30 percent. By 2001, the share for Canada plus the European nations was only 20 percent, while the U.S. share was 46 percent. In biotechnology, the most innovative pharmaceutical sector, the disparity is even greater. In 2002, biotechnology revenues in the United States were approximately \$16.5 billion, compared to about \$5 billion for the five largest European nations combined (Jones and Bate 2003). In particular, U.S. sales were about 25 times those in the U.K.

The primary source of R&D investment, however, is not revenues but profits (Scherer 2001). Because revenues must cover marginal costs of manufacturing, distribution, and overhead, which tend to be of roughly comparable levels across nations, we would expect that the American share of profits would be greater. The facts seem to bear this out. A recent analysis concluded that in 1992, Europe accounted for 33 percent of the global pharmaceutical profit pool, but by 2002, its share had fallen to only 18 percent. In 1992, the U.S. enjoyed 47 percent of global profits from pharmaceuticals. In 2002, it accounted for 62 percent of profits.⁹

5. Relative simple changes could substantially reduce actual and potential free-riding by wealth nations

Like most economists, I think that price controls are almost always a very bad idea, invariably leading to pernicious long-run consequences. Pharmaceuticals are an especially unfortunate target for price controls. In most markets, price controls generate shortages and other obvious distortions, which may inspire measures to relax or even bring an end to controls. An example of ameliorating measures are the annual

⁹ Data from *Medical and Healthcare Marketplace Guide*, as cited by Gilbert and Rosenberg 2004.

adjustments to Medicare reimbursement levels made by CMS and Congress in the face of threats of exit by physician specialties and health care organizations. Such correctives can certainly lessen the harms from controls even if they cannot reverse them altogether. Unfortunately, the pharmaceutical R&D market does not offer this essential check on price controls. Once controls are in place, no one will be able to identify the useful pharmaceutical R&D projects that have been curtailed or prevented. Because R&D takes so long, and involves such high financial risk, there is no substitute for the market incentives of handsome profits from success and financial setback, even bankruptcy, in the face of failure. This is not an industry in which price controllers would be able to pick winners among the hundreds of potential research lines.

There is no avoiding the fact, however, that governments put themselves into a difficult position when they decide to pay for prescription drugs. If they simply pay what manufacturers demand, there is no natural limit to such demands. Hence some constraints on payments are inevitable. As we have seen, however, many of our wealthiest national competitors are constraining prices via direct controls rather than relying upon market mechanisms. The result is to reduce worldwide pharmaceutical R&D funding and to move toward free-riding on American-funded research. The best solution would be to dispense with price controls and adopt market-based cost control methods similar to those employed by large health care organizations in the U.S. The prospect for such a change seems remote, however.

Nonetheless, at least a few measures are available to wealthy nations which, if implemented, could at least reduce the current drag on innovation and the growing tendency toward free-riding.

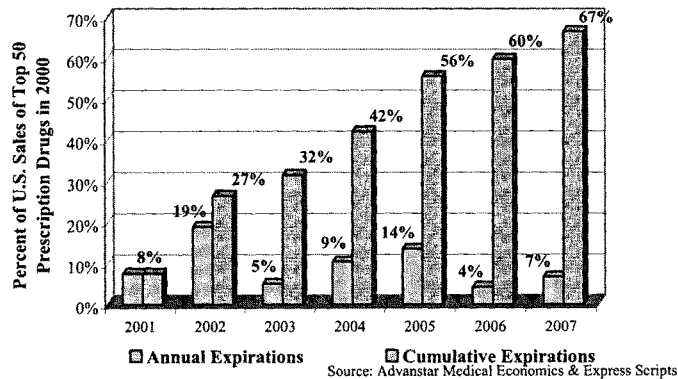
Make greater use of generics:

One tool, emphasized by former FDA Commissioner Mark McClellan, is wider use of generic drugs (McClellan, September 25, 2003). The ability of generics to reduce health care costs is almost startling. Since passage of the Hatch-Waxman Act in 1984, the generic share of all prescription has increased from 19 percent to more than 50 percent. In many respects, however, the generic revolution is just reaching maturity. The

U.S. pharmaceutical market is now in the middle of a remarkable and unprecedented surge in patent expirations of blockbuster drugs, followed by generic entry and dramatic price reductions. The overall pattern can be seen in Figure 1, which shows the proportion of total prescription drug spending in the year 2000 that has gone generic or soon will. As the chart indicates, this has been happening very roughly at about 10 percent annually, so that well over 50 percent of the year 2000 market will be generic or eligible for generic entry by the end of 2006. It is true that litigation has sometimes delayed generic entry, but it is unlikely to do so for more than a year or so in the future, and many important patent expirations are quickly followed by generic entry. This has already happened with several blockbuster drugs including Prozac (the pioneer among the dominant antidepressant category of SSRIs), Prilosec (which was the best-selling drug in the world as recently as 2000), Claritin, and such essential but less well-known drugs as Glucophage and Zestril.

Figure 1

Percent of Top 50 Prescription Drugs' U.S. Sales in 2000 for Branded Drugs with Patents Expiring 2001-2007



The U.S. has been the world leader in generic competition since passage of the Hatch-Waxman Act in 1984. Some nations, notably Canada and the U.K., have nearly

caught up. Several other economically advanced nations, however, impose substantial barriers to generic competition. In fact, stringent price controls tend to work to the disadvantage of generics. In their study of the competitive effects of price controls and other regulations, Danzon and Chao (2000, p. 311) concluded, “We find that price competition between generic competitors is significant in unregulated or less regulated markets (United States, United Kingdom, Canada, and Germany) but that regulation undermines generic competition in strict regulatory systems (France, Italy, and Japan).” In their recent analysis of international pharmaceutical prices, Danzon and Furukawa (2003, p. 525) noted, “...total generic share of unit volume is low in the price-regulated markets of France (28 percent), Italy (34 percent), and Japan (40 percent), and higher in countries with freer pricing such as the United States (58 percent), Germany (61 percent), and the United Kingdom (49 percent).” They also noted that price controls and other regulations in some nations, notably France and Italy, have traditionally discriminated against generic entry by foreign manufacturers while favoring domestic manufacturers. The result is that generics are often priced at levels comparable to those for branded drugs.

This mix of lower prices for innovative drugs and higher prices for old generics amounts to a bias against rewarding R&D. The prospect for a better trade-off, one that encourages rather than penalize pathbreaking research, is enticing. Former FDA Commissioner McClellan (Sept. 25, 2003) pointed out that these and other nations could relax some controls in order to curtail the tendency toward international free-riding while also saving money on generics.

Permit a more efficient pharmacy retailing sector:

Some nations impose regulations that limit competition or otherwise raise retail pharmacy prices. Danzon and Chao (2000, p. 311) note, “Regulation of retail pharmacy further constrains competition in France, Germany, and Italy.” Kanavos (2004) has estimated that anti-competitive regulations in European nations often increase retail prices on the order of 15 percent or more. Germany is an example of this phenomenon. German fixes pharmacy retail margins and prohibit discounts while also restricting entry.

This arrangement leaves pharmacies with little incentive to obtain lowest-cost pharmaceuticals including generics. This arrangement has been noted by many observers, including the German Department of Health, which has undertaken measures to encourage pharmacies to obtain supplies from lower-cost sources. Anti-competitive retail pricing extends beyond the European mainland. Australian authorities recently refused to reconsider regulations that restrict competition so as to increase price pharmacy prices by 15 percent.

Eliminate heavy-handed disincentives for the use of innovative drugs:

In the French price controls system, the government reimburses nearly the full price, with minimal patient copays, if the manufacturer agrees to the government's price ceiling. If the manufacturer charges more than the ceiling price, the patient must pay the entire price (rather than a higher copay, as is the practice with American managed care systems). The effect is that even if the patient and his or her physician believes a newer drug has a decisive advantage, worth more than the difference in price between the two drugs, the patient is forced to pay far more than the difference in price. This kind of disincentive to using innovative drugs could be dismantled. That would probably raise prices somewhat as manufacturers would be in a better position to resist sub-market price controls. However, it would end what is presently a very unwise trade-off in which health care costs are moderately suppressed at the cost of rewarding competition within a therapeutic category. As recent developments in the market for the statin class of cholesterol-reducing drugs have demonstrated, post-approval research within a therapeutic category can yield extremely valuable medical advances (Topol 2004). Denying rewards for such progress makes little sense.

Permit direct-to-consumer advertising of prescription drugs:

Direct communication to patients is an escape valve around harmful price controls. The experience of two nations, the United States and New Zealand, has demonstrated that direct-to-consumer advertising of prescription drugs yields substantial benefits with little harm. Among the benefits are information about newly approved

drugs, improved treatment regimens, and better compliance with prescribed therapies (Calfée 2003). The blanket prohibition on DTC advertising in Canada, Europe, and Australia appears to have little basis beyond a desire to curtail a tool that may increase health care costs even as it improve patient health.

Provide for greater medical and patient input in setting prices:

The FDA has greatly improved the new drug approval process by systematically drawing on the experience and expertise of academic, medical practitioners, and patient groups. A comparable arrangement may improve the registration component in the price controls systems of Europe, Australia, and others. The opportunity for public scrutiny and comment by those with both expertise and a direct stake in the benefits of innovative drugs might reduce the probability of opportunistic price-setting policies that threaten to increase the size and scope of free-riding pharmaceutical R&D supported by revenues in the U.S. market.

Explore PBM-like arrangements for negotiating drug prices:

In the United States, pharmaceutical benefit managers provide a potent free-market tool for reducing pharmaceutical costs with little sacrifice in medical benefits from innovation. This process could offer valuable experience, and perhaps a model, for price negotiations elsewhere. Among the potential benefits could be far more aggressive use of generics.

Abjure the threat of compulsory licensing when negotiating prices:

Although wealthy nations have avoided invoking the threat of compulsory licensing since the early 1980s, some people believe the threat remains in place. Except in short-run emergencies when supply problems arise unexpectedly, there is little reason even to hold compulsory licensing in reserve. As long as nations avoid shipping lower-priced drugs to the U.S. market, firms will feel reasonably confident in selling at lower prices where per capita incomes are less than in the U.S. The possibility that manufacturers of patented drugs will simply refuse to work their patents (legal term)

despite price ceilings that bear a reasonable relationship to per capita incomes, appears to be remote. On the other hand, the threat of compulsory licensing, which amounts to abrogation of fundamental patent rights, creates downward pressure on the expected rewards to innovation and therefore at least marginally reduces R&D incentives.

References

- Calfee, John E. (2000) *Prices, Markets, and the Pharmaceutical Revolution*. American Enterprise Institute, Washington, D.C. Available at www.aei.org/publications/filter_bookID.196/book_detail.asp. Accessed January 4, 2004.
- Calfee, John E. (2001) "Pharmaceutical Price Controls and Patient Welfare," *Annals of Internal Medicine*, v. 134, n. 1 (June 5), p. 1060-1064.
- John E. Calfee (2003) "What Do We Know About Direct-To-Consumer Advertising Of Prescription Drugs?," *Health Affairs*, p. W3 116-119 (web exclusive), Feb. 26.
- Cambridge Pharma Consultancy (2002) ___
Consumer Checkbook, "Prescription Drugs: Smart Shopping Yields Big Savings," available at www.checkbook.org.
- Danzon, Patricia M. (1997) *Pharmaceutical Price Regulation: National Policies versus Global Interests*, AEI Press, Washington, D.C.
- Danzon, Patricia M. (2000) "The Pharmaceutical Industry," in *The Encyclopedia of Law and Economics*, eds. B. Bouckaert and G. de Geest. Cheltenham: Edward Elgar.
- Danzon, Patricia M., and Li-Wei Chao (2000) "Does Regulation Drive out Competition in Pharmaceutical Markets?," *Journal of Law and Economics*, v. 32, n. 2, p. 311-357 (Oct.).
- Danzon, Patricia M., and Michael F. Furukawa (2003) "Prices And Availability Of Pharmaceuticals: Evidence From Nine Countries," *Health Affairs*, web exclusive, 29 October 2003, p. w3 521-536.
- Danzon, Patricia M., and Jonathan D. Ketcham (2003) Reference Pricing of Pharmaceuticals for Medicare: Evidence from Germany, the Netherlands and New Zealand," NBER Working Paper 10007, Sept.; forthcoming in forthcoming in Volume 7 of "Frontiers in Health Policy Research."

- Danzon, Patricia M., and Adrian Towse (2003) "Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents," *International Journal of Health Care Finance and Economics*, v. 3, p. 183-205.
- Danzon, Patricia M., Richard Wang, and Liang Wang (2002) "The Impact of Price Regulation on the Launch Delay of New Drugs: A Study of Twenty-Five Major Markets in the 1990s," working paper, Health Care Systems Department, The Wharton School, University of Pennsylvania.
- Ellison, Sara Fisher, and Wallace P. Mullin (2001) "Gradual Incorporation of Information: Pharmaceutical Stocks and the Evolution of Clinton's Health Care Reform," *Journal of Law and Economics*, v. 44, n. 1, p. 89-129 (April).
- Echikson, William (2003) "European Commission Moves To Ease Curbs on Drug Prices," *Wall Street Journal*, July 2, 2003.
- European Federation of Pharmaceutical Industries and Societies (EFPIA), "The Pharmaceutical Industry in Figures: Key Data, 2003 Update," p. 4.
- Frank, Richard G. (2001) "Prescription Drug Prices: Why Do Some Pay More Than Others Do?" *Health Affairs*, vol. 20, no. 2 (March-April), p. 115-128. Available (for subscribers) at content.healthaffairs.org/cgi/reprint/20/2/115.pdf
- Frank, Richard G. (2003) "Government Commitment And Regulation Of Prescription Drugs," *Health Affairs*, v. 22, n. 2, p. 46-48 (May-June).
- Gilbert, Jim, Preston Henske, and Ashish Singh (2003) "Rebuilding Big Pharma's Business Model," *InVivo*, Nov. 2003 (summarizing portions of the "Bain Report".)
- Gilbert, Jim, Preston Henske, and Ashish Singh (2004) "Imbalanced Innovation: The High Cost of Europe's 'Free Ride'," summarized in *In Vivo: The Medicine & Business Report*, vol. 22, no. 3. March 2004 (also based on a report from Bain Consulting).
- Graham, John R. "Prescription Drug Prices in Canada and the United States: Canadian Prescriptions for American Patients Are Not the Solution." *Public Policy Sources*, no. 70 (Sept. 2003).

- Jones, Carole, and Guy Bate (2003) "At the 20 Year Milestone for Biotechnology - a Performance Review," in *BioCommerce Data's Biotechnology Company Compendium 2002/2003*.
- McClellan, Mark (2003) "Remarks before the First International Colloquium on Generic Medicine," Cancun, Mexico, September 25, 2003.
- Newhouse, Joseph P. (2004) "How Much Should Medicare Pay for Drugs?" *Health Affairs*, vol. 23, no. 1 (January-February), pp. 89-102.
- Scherer, Frederick M. (2001) "The Link Between Gross Profitability and Pharmaceutical R&D Spending," *Health Affairs*, v. 20, n. 5, p. 216-220 (Sept.-Oct.).
- Vernon, John (2004) "Examining the Link Between Price Regulation, Reimportation, and Pharmaceutical R&D Investment," AEI-Brookings Joint Center, forthcoming in *Health Economics*.
- Wagner, Judy, and Elizabeth McCarthy (2004) "International Differences in Drug Prices," *Annual Review of Public Health*, v. 25, p. 475-495.

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Responses to Questions for the Record
Before the
United States Senate Committee on Finance
Joint Subcommittees on International Trade and Health
In connection with April 27, 2004 Public Hearings on
International Pharmaceutical Prices

May 20, 2004

This is in response to Senator Grassley's April 3, 2004 letter in which Committee members asked the following question:

Some suggest that R&D by government agencies can replace that done by private companies. Can you explain whether and how technological advances are aided or hindered by the ability to make a profit? Do you believe that the same numbers and variety of innovative drug therapies would be developed if most or all R&D were done by government agencies?

Here are my responses to the two issues raised in that question.

A. "Can you explain whether and how technological advances are aided or hindered by the ability to make a profit?"

Virtually all economists who study the economics of innovation agree that profits have an effect on technological advances, and that as a general rule technological

advances are aided by the prospect of gaining profits from creating and furthering such advances. This thinking is embedded in Article 1, Section 8 of the U.S. Constitution, which states, "The Congress shall have power to . . . promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

The relationship between profits and technological advances operates on at least two levels. One is the connection between profits and private property. It is obvious that owners have no incentive to maintain and develop land and buildings if others can appropriate the fruits of their work. The same is true of technological advances that are reached after the expenditure of much time, effort, and money. If competitors can imitate or appropriate those inventions without the permission of their creators, inventors will have little incentive to develop products incorporating technological advances even if those products would be extremely valuable to society. The same problem can arise in connection with inventions that are provided via public funding but require additional investment to be made useful. Again, the prospect of profits is usually necessary to generate the necessary investment. An obvious example is molecules that might prove to be useful medical therapies. Even after the molecules have been discovered by public funds, large additional investments are necessary to learn whether the potential drugs will actually perform sufficiently well to obtain FDA approval.

One might think that if public funding were sufficiently large and reliable, these problems would disappear and the profit motive would be rendered unnecessary. This raises a second fundamental relationship between technological advances and the profit motive. Technological advances often involve a great deal of uncertainty and, therefore, financial risk. It is usually impossible to predict with reasonable certainty whether a large investment in a specific line of research will generate corresponding benefits. History documents that the discipline of the marketplace is necessary to avoid wasteful or inordinately slow R&D. In addition, public funding of large research projects can attract or create special interests, which can impede reasonably efficient exploitation of the potential benefits of new technology. Thus when one moves beyond basic research

(where the profit motive is usually weak because most important discoveries tend to serendipitous or nearly so), nearly all practical advances based upon new technology around the world have tended to emerge from profit-seeking enterprises.

B. “Do you believe that the same numbers and variety of innovative drug therapies would be developed if most or all R&D were done by government agencies?”

I do not think that government agencies could develop innovative drugs in numbers or varieties comparable to what the private sector would produce. The main reason is that the problems just outlined apply with special force to the creation of new drugs. Even with large doses of funding, market discipline is essential. A large number of potential drugs are already available for testing, and many more can easily be discovered using current methods for discovering drug targets and the molecules or biologicals that could address those targets. There is no substitute for the market in deciding how to allocate tens of billions of research monies every year. Those amounts, large as they are, pale before the costs of following up on each and every promising lead. The unavoidable financial risks of drug development require not only that successes be rewarded, but also that failures be penalized. The market does both, whereas the government tends to do neither.

An example of the problems with publicly supported drug research are recent events in the long search for a vaccine for HIV-AIDS. A very expensive NIH-WHO trial of an AIDS vaccine in Thailand is proceeding not because the NIH still believes in the vaccine's once-promising technology (quite the contrary -- most researchers inside and outside of NIH expect failure) but because the U.S. must maintain “credibility” as a funder of international trials.

Past experience with publicly conducted drug development is illuminating. Very few new drugs in recent decades have emerged from the efforts of NIH, from government agencies in other nations, or from non-governmental non-profit organizations. This is not

for lack of opportunity, as there are no significant barriers (beyond funding and motivation) confronting any such organizations that wish to conduct clinical trials and pursue FDA approval of new drugs. What is missing the ability to take risks and to withdraw funding when things are not working out as hoped.

Hence I think that publicly funded drug development would generate neither the variety nor the quantity of new drugs that are likely to emerge from private development in the competitive pharmaceutical R&D market. One further issue needs to be addressed, however. This is the argument that private markets do not generate the right kinds of drugs: too few drugs for rare diseases, and too many so-called “me-too” drugs for common conditions. I think it very unlikely the government agencies could improve upon the private market, however. The Orphan Drug law has already led to the testing of scores of drugs for rare disease. And as was pointed out in a recent *New England Journal of Medicine* article, follow-on drugs typically cater to patients poorly served by existing drugs while providing a strong dose of price competition (Lee 2003). Economists have documented that competitive market forces cause blockbuster brands to lose most of their market value before their patents expire (Lichtenberg and Philipson 2003). This reflects the force of competition from follow-on drugs.

References

Lee, Thomas H. (2003) "Perspective: 'Me-Too' Products: Friend or Foe?" *New England Journal of Medicine*, v. 350, n. 3, p. 211-212 (January 15, 2004).

Lichtenberg, Frank R., and Tomas J. Philipson (2002) "The Dual Effects of Intellectual Property Regulations: Within- and Between-patent Competition in the U.S. Pharmaceuticals Industry," *Journal of Law and Economics*, v. 45, p. 643-672 (October).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Rockville MD 20857

STATEMENT OF

**WILLIAM K. HUBBARD
ASSOCIATE COMMISSIONER FOR
POLICY AND PLANNING**

**JOINT HEARING
OF THE**

**SUBCOMMITTEE ON HEALTH CARE
AND
SUBCOMMITTEE ON INTERNATIONAL TRADE**

COMMITTEE ON FINANCE

UNITED STATES SENATE

APRIL 27, 2004

Release Only Upon Delivery

INTRODUCTION

Mr. Chairman and Members of the Committee, I am William K. Hubbard, Associate for Policy and Planning at the U.S. Food and Drug Administration (FDA or the Agency). I appreciate the opportunity to testify regarding the cost of prescription drugs and the issues relating to proposals that would legalize the importation of prescription drugs into the United States. Although FDA has very limited expertise in the area of international pharmaceutical trade, we are happy to provide our perspective on the health and safety issues that are implicated in the importation of pharmaceutical products into the United States.

At FDA, our statutory responsibility is to assure the American public that the drug supply is safe, secure, and reliable. For more than 60 years, the Federal Food, Drug, and Cosmetic (FD&C) Act has ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness and preventing complications. In carrying out this responsibility, FDA also works to do all we can under the law to make medicines accessible and help doctors and patients to use them as effectively as possible, through such steps as expanding access to generic medicines, reducing the time and cost of showing that new medicines are safe and effective, and providing up-to-date information for health professionals and patients to obtain the benefits and avoid the risks associated with powerful medicines. That is the primary mission of the thousands of dedicated staff,

including leading health care experts, doctors, economists and scientists who work tirelessly at FDA in public service for the American people. FDA has substantial concerns about unapproved, imported pharmaceuticals whose safety and effectiveness cannot be assured because they are outside the legal structure and regulatory resources provided by Congress. We have also taken steps within the law to improve the availability of affordable medicines and reduce drug costs, without compromising safety. In my testimony today I look forward to having the opportunity to engage in a constructive dialogue about the issue of importing prescription drugs as well as discussing steps to provide greater access to more affordable prescription medications.

REDUCING DRUG COSTS

FDA shares with Congress its great concern for senior citizens and other patients who have difficulty paying for prescription drugs. That is why the Administration worked with Congress to enact the new Medicare prescription drug law. And that is why FDA has made it a priority for its medical and scientific experts to establish and expand programs that promote access to innovative treatments to help Americans live healthier lives and assure that Americans have access to medications and treatments that they can afford.

FDA has taken a number of significant steps to provide greater access to affordable prescription medications, including unprecedented steps to lower drug costs by helping to speed the development and approval of low-cost generic drugs after legitimate patents

have expired on branded drugs. Generic drugs typically cost 50 to 70 percent less than their brand-name counterparts. On June 18, 2003, FDA published a final rule to improve access to generic drugs and lower prescription drug costs for millions of Americans. These changes will save Americans over \$35 billion in drug costs over the next 10 years, and will also provide billions in savings for the Medicare and Medicaid programs. Elements of this rule were codified as part of the recently enacted Medicare law and, with FDA's technical assistance, the law added additional mechanisms to enhance generic competition in the marketplace.

In addition, last year the Administration supported and Congress enacted an increase of \$8 million for FDA's generic drug program, the largest infusion of resources into this program ever. This increase in the generic drug budget enables FDA to hire additional expert staff to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. Improvements in the efficiency of review procedures have led to significant reductions in approval times for generic drugs since 2002, and consequently will save consumers billions more by generally reducing the time for developing generic drugs and making them available.

The Agency has also taken steps to help improve the development process to help lower the high cost of developing new drugs. In particular, FDA is continuing to improve the methods by which assistance and advice is provided to sponsors regarding what we believe are the best approaches to develop new therapies and maximize the prospects for swift FDA approval. These ongoing efforts are designed to provide sponsors with the

best possible information and thus increase the efficiency of the development process. We expect that reforms in drug and biologic manufacturing requirements should help reduce manufacturing costs by 20 percent. FDA has identified several priority disease areas, such as cancer, diabetes and obesity, and new technologies including gene therapy, pharmacogenomics and novel drug delivery systems that are good candidates for efforts to clarify regulatory pathways and clinical endpoints.

FDA is also working to prevent adverse events through new rules that would require bar coding for drugs and better ways to track adverse events automatically with the goal of preventing billions of dollars in unnecessary health care costs each year. FDA's final rule requiring bar coding of drug is estimated to have net economic benefits of approximately \$3.5 billion per year. Avoiding such preventable medical complications will also help reduce health care costs, while enhancing quality and safety. In addition, the Agency is striving to promote electronic prescribing, to improve quality and reduce prescription costs as well.

IMPORTATION OF PRESCRIPTION DRUGS

Sixty-five years ago, Congress responded to widespread instances of unsafe drugs by directing FDA to create a system for assuring that Americans have a drug supply they can trust will not harm them. Over forty years ago, Congress required that legal drugs be proven to be effective as well, because modern medicines – when they are produced, distributed, prescribed, and used properly – should not only be safe but also should

prevent the many complications and side effects of diseases. More recently, in 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent substandard, ineffective, or counterfeit drugs from entering the U.S. Under PDMA, it is illegal for anyone other than the drug's original manufacturer to re-import a prescription drug into the U.S. that was manufactured in the U.S. This law was enacted with strong bipartisan support because of high-profile cases of unsafe and ineffective drugs entering the U.S. in large volumes. In one instance, over 2 million unapproved and potentially unsafe and ineffective Ovulen-21 "birth control" tablets from Panama were distributed throughout the U.S. In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, found its way into the U.S. drug distribution from a foreign source. Over the years, FDA's dedicated professional staff has employed PDMA and other authorities to build a drug safety infrastructure to ensure that Americans enjoy the highest-quality drug supply in the world.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This is evident in the recent significant increase in efforts to introduce counterfeit drugs into the U.S. market. FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990s. Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. For example, FDA recently worked with domestic and international authorities to shut down a website that

was advertising “FDA-approved” and safe “European” birth control pills and other drugs, but was actually responsible for importing ineffective, counterfeit drugs. Evidence strongly suggests that the volume of these foreign drug importations is increasing steadily, presenting an increasingly difficult challenge for Agency field personnel at ports-of-entry, mail facilities, and international courier hubs, and our laboratory analysts and border and law enforcement partners.

FDA is doing its best to use its limited international authorities and resources to stop the increasing flow of violative drugs into this country, but the task is daunting. Each day, thousands of individual packages containing prescription drugs are imported illegally into the U.S. FDA’s Office of Regulatory Affairs has inspectors who work in the field who perform investigational work pertaining to imported prescription drugs, a job that is not limited to inspections at ports-of-entry.

SAFETY CONCERNS RELATING TO IMPORTATION

FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired,

subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.

Patients also are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the operator of the pharmacy often is not known, or the physical location of the seller is unknown or beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. However, this system, as it works today, is already overwhelmed by the number of incoming packages, and this presents a significant ongoing challenge for the Agency.

Recent spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. In 2003, inspectors found that the majority of the packages examined in these “blitzes” contained illegal, unapproved drugs. Last summer, FDA and CBP conducted blitz examinations on mail shipments at the Miami and New York (JFK) mail facilities in July, and the San Francisco and Carson, California, mail facilities in August. In each location, the agencies examined packages shipped by international mail over a 3-day time span. Of the 1,153 shipments examined, the overwhelming majority (1,019 packages, or 88 percent) contained unapproved drugs. The drugs arrived from many countries. For example, 16 percent entered the U.S. from Canada; 14 percent were from India; 14 percent came from Thailand, and 8 percent were shipped from the Philippines.

A second series of import blitz exams, conducted in November 2003, also revealed potentially dangerous, illegally imported drug shipments. Of the 3,375 products examined, 2,256 or 69 percent were violative. FDA found recalled drugs, drugs requiring special storage conditions and controlled substances. These blitz exams were

performed at the Buffalo, Dallas, Chicago and Seattle international mail facilities and, for the first time, the private courier hubs at Memphis and Cincinnati. Canadian parcels appeared most frequently (80 percent of the mail parcels), while 16 percent were from Mexico, and the remaining 4 percent came from Japan, the Netherlands, Taiwan, Thailand and the United Kingdom.

Examples of the potentially hazardous products encountered during the exams include:

- Unapproved drugs such as 1) anti-azathioprine an immunosuppressant drug that can cause severe bone marrow depression and can be associated with an increased risk of infection and cancer development; and 2) human growth hormone, which can have serious side effects if used inappropriately or in excessive doses.
- Controlled substances – FDA and Customs found over 25 different controlled substances were found, including Diazepam; Xanax; Codeine; Valium Lorazepam, Clonazepam and anabolic steroids.
- Drugs withdrawn from the U.S. market for safety reasons such as Buscapina, which appears to be the drug dipyrene, removed from the market in 1977 due to reports of association with agranulocytosis -- a sometimes fatal blood disease.
- Improperly packaged drugs shipped loose in sandwich bags, tissue paper or envelopes.

- Animal drugs not approved for human use such as Clenbuterol, a drug approved for the treatment of horses but also known as a substance of abuse in the “body building” community and banned by the International Olympic Committee.
- Potentially recalled drugs -- American consumers were sent Serevent Diskus and Flovent Diskus medicines from Canada for the treatment of asthma. Shortly after the blitz, certain lots of the Canadian versions of these drugs were recalled in Canada.
- Drugs requiring risk management and/or restricted distribution programs -- For example, Canadian-manufactured isotretinoin, which in the U.S. is subject to a stringent risk management plan, under which prescribers are required to screen, educate and monitor patients to avoid certain serious risks such as birth defects.
- Drugs with inadequate labeling such as those with missing dosage information or labeling that is not in English.

But its not just FDA that has identified both legal and safety concerns about importation of prescription drugs, so have many other professional regulators, including state pharmacy boards and most recently courts. On November 6, 2003, Federal District Court Judge Claire V. Eagan, U.S. District Court for the Northern District of Oklahoma, issued a decision in United States v. RX Depot, Inc. and RX of Canada LLC, granting a preliminary injunction to immediately prevent these defendants who operate business that

import prescription drugs from Canada, because such unapproved drugs were a clear violation of the FD&C Act. In addition to her unequivocal findings of law, the Judge concluded that these companies could not assure the safety of the drugs they have been importing and, as a result, in violating the law have put Americans at serious risk. The Judge concluded that “unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer does not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration.” She continues: “Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States.”

RECENT STATE ACTIONS

Despite this ruling and the concerns raised by the Agency, recently, several governors and mayors have proposed to create systems whereby their employees and/or constituents could be directed to Canadian pharmacies for purchasing Canadian drugs. FDA has spoken with a number of such officials about our concerns, and many have declined to proceed and have turned to other legal, proven ways to safely reduce drug costs. However, some states and localities, including the state of Minnesota and the state of Wisconsin have proceeded to establish state run websites linking citizens to entities dispensing drugs purportedly from Canada.

Recent research by the state of Minnesota pointed out significant problems related to purchasing non-FDA approved pharmaceuticals from foreign Internet pharmacies. Even Canadian pharmacies that participate in the Canadian Internet Pharmacy Association were observed engaging in problematic practices during a single, voluntary, pre-announced "visit" by Minnesota State officials. Minnesota State health officials noted dozens of safety problems, such as:

- 1) several pharmacies used unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify prescription questions;
- 2) one pharmacy had its pharmacists review 100 new prescriptions or 300 refill prescriptions per hour, a volume so high that it would have been impossible to assure safety;
- 3) one pharmacy failed to label its products, instead it shipped the labels unattached in the same shipping container, even to patients who received multiple medications in one shipment; and
- 4) drugs requiring refrigeration were being shipped un-refrigerated with no evidence that the products would remain stable.

At least one of the Canadian pharmacies visited by Minnesota health officials dispensed many drugs that apparently were not even of Canadian origin, and many of the drugs were obtained from prescriptions that had been written and rewritten across multiple Canadian provinces. These types of systematic safety problems, which appear to be a common way of doing business, would generally be clear regulatory violations that

would not be tolerated under the comprehensive system of Federal and state regulation of drug safety in the U.S.

DRUG COUNTERFEITING

In addition, counterfeiting of prescription drugs is a growing global concern. In fact, counterfeiting of drugs is commonplace in many countries. In the U.S. counterfeiting of drugs has been kept to a minimum because of our extensive system of laws, regulations, and enforcement by Federal and state authorities. As a result, Americans have a high degree of confidence in the drugs they obtain from their local pharmacy. In recent years, however, FDA has seen growing evidence of efforts by increasingly well-organized counterfeiters, backed by increasingly sophisticated technologies and criminal operations, intent on profiting from drug counterfeiting at the expense of American patients.

To respond to this emerging threat, FDA convened a Counterfeit Drug Task Force that received extensive comment and ideas from security experts, Federal and state law enforcement officials, technology developers, manufacturers, wholesalers, retailers, consumer groups, and the general public. Based on these comments, on February 18, 2004, FDA issued a report that contains specific steps that can be taken now and in the future to protect consumers from counterfeit drugs and secure the U.S. drug supply chain.

The report's framework describes how to strengthen our drug safety assurances against modern counterfeit threats through a multilayered strategy that includes modern anti-

counterfeiting technologies. Promising developments such as “track and trace” technologies that cannot be faked like a paper drug pedigree, and verification technologies built not only into tamper-resistant drug packaging but also into the drugs themselves will make our job of verifying the legitimacy of drug products much easier. FDA is working to speed the availability of these anti-counterfeiting technologies, but these technologies have not yet been proven, and they are intended to complement and reinforce an underlying system for assuring the safety and effectiveness of prescription drugs.

Thus, anti-counterfeiting technologies hold great promise for strengthening our legal drug distribution system, but to be effective they must be used in conjunction with effective legal authorities.

IMPORTATION PROPOSALS

At a time when FDA faces more challenges than ever in keeping America’s supply of prescription drugs safe and secure, legislation to liberalize drug importation without providing concomitant enhancements in FDA’s authorities and resources to assure the safety of these imports could seriously compromise the safety and effectiveness of our drug supply. The volume of importation that could result from enactment of these bills could overwhelm our already heavily burdened regulatory system. Many of these bills fail to provide FDA with adequate authority or resources to establish and regulate the major new “legal” channels for incoming foreign drugs - manufactured, distributed,

labeled, and handled outside of our regulatory system - or even to ensure their safety. Some of these proposals would even limit FDA's existing authorities, which are already being stretched. They would impose unprecedented restrictions on FDA's ability to inspect and test drugs, and FDA's authority to block the distribution of drugs we think are unsafe.

Today, FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import drugs into the U.S. The drugs must be produced in FDA inspected facilities. These facilities and the drugs produced in them are currently covered by the U.S. regulatory system, and it is legal to import these drugs.

We want to be clear that our objections to legislative proposals that would create large, legal channels for drugs to enter our drug supply without assurances of safety are based on concerns that they will create substantial drug safety problems without clear, large-scale, long-term benefits. FDA has particularly raised concerns about legislative proposals that would create such channels by weakening our existing safety protections rather than providing the necessary resources or additional authorities to enable the Agency to assure drug safety and security. Furthermore, our economic experts as well as many others have raised concerns about the limitations of potential longer-term benefits and savings that could be realized from imported drugs. The Congressional Budget Office has estimated that the savings from even broad, multiple-country importation

proposals would be smaller than can be obtained through the generic drug reforms that Congress and FDA are in the process of implementing now. Even the Canadian Internet pharmacy operators have said that they cannot provide safe drugs for Americans on a large scale. These are important concerns, but that does not mean that we are opposed to undertaking a thorough effort to determine whether and how importation could be accomplished safely. But this cannot be accomplished by fiat or with a presumption of safety.

Some Members of Congress are working on the difficult challenge of identifying the resources and authorities necessary to assure safety for certain types of imported drugs. This is a much more constructive approach than simply declaring imported drugs to be legal or restricting FDA's authorities to keep the U.S. drug supply safe. To help determine whether and what specific authorities and resources would provide for the safe importation of drugs, the conference report of the new Medicare law gave the Secretary of Health and Human Services specified requirements for a study of drug importation. Among these requirements, the conference report asked the Secretary to "identify the limitations, including limitations in resources and in current legal authorities, that may inhibit the Secretary's ability to certify the safety of imported drugs" and to "estimate agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country."

MEDICARE IMPORTATION STUDY AND TASK FORCE

Last year, when Congress enacted the Medicare Modernization Act, it recognized these safety issues and included language that required that the Secretary certify the safety of prescription drugs prior to authorizing their importation. At the same time, Congress directed the Department to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. The Department is currently working on that analysis and has created an intergovernmental task force to steer this effort to completion by the Congressional deadline later this year.

The taskforce includes representatives from FDA, the Centers for Medicare and Medicaid Services, Customs and Border Protection, and the Drug Enforcement Administration.

The taskforce is bringing together a wide variety of health care stakeholders to discuss the risks, benefits and other key implications of the importation of drugs into the U.S., and to offer recommendations to the Secretary on how to best address this issue in order to advance the public health. The statutory language and the conference report provide detailed, comprehensive requirements for the importation study.

As an integral part of the study process, the task force is holding a series of meetings to gather information and viewpoints from consumer groups, health care professionals, health care purchasers, industry representatives and international trade experts. This process affords Congress and the Administration an opportunity to fully address the

complex public health, economic and legal questions in order to make appropriate and effective recommendations about importation of prescription drugs and the associated fundamental changes to the FD&C Act and in safety resources that may be required.

CONCLUSION

The standards for drug review and approval in the U.S. are the best in the world, and the safety of our drug supply mirrors these high standards. The employees of FDA constantly strive to maintain these high standards. However, a growing number of Americans are obtaining prescription medications from foreign sources. U.S. consumers often seek out Canadian suppliers, sources that purport to be Canadian, or other foreign sources that they believe to be reliable. While some foreign drug manufacturers submit their products to FDA for approval, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports-of-entry are often unapproved drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources.

The vigilance of FDA and BCBP inspectors is an important tool in detecting imported products that violate the FD&C Act. Given the available resources and competing priorities facing these agencies, however, experience shows that inspectors are unable to visually examine many of the parcels containing prescription drug products that arrive through the mail and private courier services each day. The growing volume of

unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable challenge.

FDA firmly believes that we can and should do a much better job of making safe and innovative drugs more affordable in the United States, but to succeed we need to find safe and affordable solutions that, when implemented, do not put consumers at risk. We appreciate and support the bipartisan commitment to making drugs more affordable for seniors and other consumers and are working hard to achieve the goals of safety and affordability. We believe that Americans should not have to settle for less.

We all agree more needs to be done to continue to address the high cost of prescription medicines. But we must be cautious and deliberate as we consider proposals to accomplish this goal. FDA would urge that Congress ensure that any changes to our drug regulation system do not require American citizens to give up the “gold standard” in drug safety that has become a hallmark in this country. FDA’s scientists, doctors, health care experts and regulators must be empowered to protect us from bad medicine. We owe it to patients today and tomorrow to make our medical future brighter, healthier and more affordable.

Thank you for the opportunity to testify. I look forward to responding to any questions you may have.

RESPONSES TO QUESTIONS FROM SENATOR KYL

Question 1. In the seizure of drugs that have been reimported or imported from other countries to the United States, has the FDA tested the quality and substance of the so-called analogous drugs for their chemical equivalency? If so, what are your findings and when will they be available to the public?

Answer. The Food and Drug Administration (FDA) does not conduct routine laboratory analyses of products detained at U.S. borders. However, a recent example described below, in which laboratory analysis of imported drugs was conducted, illustrates FDA's concerns about the quality of drugs imported by U.S. consumers from abroad. We also note that recent spot examinations, or "blitzes," of foreign drug shipments to U.S. consumers conducted by FDA and U.S. Customs and Border Protection revealed that the vast majority of these packages contained illegal, unapproved drugs. Information about these examinations, and about other instances of problem foreign drugs, such as counterfeit birth control patches that contained no active ingredient, are posted on FDA's website.

Within the last six months, FDA has examined two websites having identical web pages headlined "Canadian Generics," which were identified through spam e-mails sent to consumers. FDA has purchased prescription drugs from both of these sites, and has found that these drugs and the manner in which they are sold pose potential threats to the health and safety of consumers.

There is at least one Canadian flag on every page of these sites, as well as the words "Canadian Generics." The websites say, "Order Canadian to get the biggest discounts!" Both of the URLs from which the orders were placed suggest the sites are located in, and operated out of, Canada. Despite these representations, however, we determined there is no evidence that the dispensers of the drugs or the drugs themselves are Canadian. Theregistrants, technical contacts, and billing contacts for both websites have addresses in China. The reordering website for both purchases and its registrant, technical contact, and billingcontact have addresses in Belize. The drugs were shipped from Texas, with a customer service and return address in Florida.

FDA purchased drugs described by the website as generic Viagra, generic Lipitor, and generic Ambien. None of these products, however, has a generic version approved in the U.S. or Canada. Both times, to obtain the drugs, an FDA investigator posed as a consumer and filled out an on-line questionnaire. The investigator was never asked to provide a prescription. After each purchase, the drugs arrived packaged in heat-sealed plastic bags within a manila envelope.

Ambien is a controlled substance with a substantial potential for addiction. In addition, for both purchases, FDA's "consumer" said in the on-line questionnaire that he is taking erythromycin: The use of Viagra with erythromycin is contraindicated and, more importantly, there is a warning on the approved labeling for Lipitor about concurrent administration of Lipitor with erythromycin. Despite these critical safety issues, the website operators sent the drugs anyway.

The drugs received from the second purchase were tested in an FDA laboratory. All three samples failed, using the brand-name manufacturer's methodology. While all three samples had some level of active ingredient, the "generic" Lipitor and Viagra were found to be subpotent, while the "generic" Ambien was found to be superpotent. Two of the three drugs failed the dissolution parameters of the brand-name drugs. The third drug passed the dissolution testing, but only because it was superpotent. Two of the three samples also failed purity testing, while all three samples failed the USP criteria for content uniformity.

Question 2. There has been considerable discussion about the FDA's role in guaranteeing the safety of drugs that are imported from countries such as Canada or Mexico, because of the very high standard that has been set for pharmaceutical manufacturing, distribution and storage. While I am not suggesting that we move towards the path of importation, I would like for you to set a framework for the discussion of how a United States agency, the FDA, would manage from afar the operations in another country?

Answer. The practical problems associated with ensuring the safety and quality of drugs imported from foreign pharmacies and wholesalers are substantial, because FDA and state boards of pharmacy do not have authority over the drug distribution chain outside the U.S., nor does FDA have the ability to monitor and regulate the manufacture of drugs intended for markets other than the U.S.

Foreign pharmacies and wholesalers are not subject to FDA or state oversight, not licensed in the U.S., not subject to review or inspection by U.S. regulatory bodies, not required to meet U.S. standards for storage and safe handling of drug products, and not subject to U.S. penalties for failure to comply with Federal or state requirements. The drug distribution system as it exists today is a "closed" system. Most

retail stores, hospitals, and other outlets obtain drugs either directly from the drug manufacturer or from a small number of large wholesalers. FDA and the states exercise oversight of every step within the chain of commercial distribution, thereby ensuring a high degree of product potency, purity, and quality.

Moving from the current "closed" distribution system with relatively few importers to an "open-border" distribution system would create opportunities for bringing prescription drug products into the country outside the system of safety and effectiveness monitoring overseen by FDA. It would increase the risk that counterfeit, misbranded, and adulterated drugs would show up on U.S. drug store shelves and in American homes.

With respect to manufacturing, FDA drug approvals are manufacturer-specific, product-specific, and they include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. The drugs must be produced in FDA inspected facilities. Drugs that are imported outside of this regulatory process bypass these protections, and no amount of visual inspection at U.S. borders can provide the same level assurance of safety, quality and effectiveness as FDA's drug approval process.

Last year, as part of the Medicare Modernization Act, Congress included language authorizing a program of drug importation, but only if the Secretary of Health and Human Services could certify that implementation of the program would not compromise the safety of the U.S. prescription drug supply. At the same time, Congress directed the Secretary to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. In February 2004, the Secretary created an intergovernmental task force, chaired by Surgeon General Richard Carmona, to provide that analysis and offer findings on how to best address this issue in order to advance the public health.

The task force includes representatives from FDA, the Centers for Medicare and Medicaid Services, Customs and Border Protection, and the Drug Enforcement Administration. The panel has brought together a wide variety of stakeholders to discuss the risks, benefits and other key implications of importing drugs into the U.S. As an integral part of the study process, the task force held a series of six stakeholder meetings to gather information and viewpoints from consumer groups, health care professionals, health care purchasers, industry representatives and international trade experts. A public docket for comments was opened as well. The task force is continuing its examination of these issues and working to complete its work as expeditiously as possible.

Question 3. Given the pharmaceutical industry's inability to sustain its research and development in light of international price controls, do you believe we can rely on the government to perform or sponsor research that would continue the positive trend we have seen in drug advancement?

Answer. There is no doubt that the pharmaceutical industry has contributed enormously to the development of new and improved medications. While government organizations such as the National Institutes of Health also contribute to this effort, largely through basic research, the pharmaceutical industry plays a primary role in using the knowledge gained through research to develop, test and seek regulatory approval of new drugs.

The Medicare Modernization Act (MMA) enacted last year directed the Administration to prepare a report to Congress on the importation of drugs. The statutory language and the conference report provide a detailed list of issues to be considered in the importation study. Among those issues is "an assessment of the impact on research and development—and the associated impact on consumers and patients—if importation were permitted." We understand that the Department of Commerce is studying that issue as part of their report under section 1 123 of the MMA, and that they are also working expeditiously to submit a timely report to Congress.

RESPONSES TO QUESTIONS FROM SENATOR ROCKEFELLER

Question 1. Much has been said about price controls in other countries stifling research and development on new and innovative drugs. Yet, I find it very hard to believe that raising drug prices in other countries will lead to more research and development and lower drug prices for Americans. Drug companies could use the increased revenue for additional marketing or they could simply pocket the money as profit. As a 2001 Families USA report pointed out, U.S. drug companies that market the 50 most often prescribed drugs to seniors spend almost two-and-one-half times as much on marketing, advertising, and administration as they spent on research and development—that's \$45.4 billion on marketing, advertising and administration

and only \$19.1 billion on research and development. What assurances does the FDA have that raising drug prices internationally will result in additional research and development by U.S. drug companies?

Answer. Firms' activities respond to economic incentives. Prices closer to market levels would increase the incentive to research and develop new products that could compete for these higher revenues. The magnitude and extent of drug companies' response to less stringent government price controls is being addressed in the study that the Department of Commerce is conducting in response to section 1123 of the Medicare Modernization Act.

With respect to drug pricing, some of the world's richest nations are driving the world's hardest bargains. Many high-income countries regulate their prices for new drugs by setting them equal to those in other countries that already have rigid price controls. As a result, many relatively wealthy countries are moving away from covering any significant part of the costs of pharmaceutical research and development. They are leaving those costs for others to pay. But new drugs and devices are global products—products that can and should provide similar benefits for everyone, regardless of where they live. It is important for all countries that benefit from new medicines to share the cost of developing those products.

Question 2. The new Medicare law effectively prohibits seniors from importing prescription drugs back into the United States from Canada and other countries at lower cost. Although the new law contains a provision allowing reimportation from Canada as long as the Secretary of HHS certifies the safety of such imports, HHS has long opposed the reimportation of prescription drugs from other countries. Under both the Clinton and Bush administrations, HHS has refused to implement reimportation laws, maintaining that it cannot certify the safety of reimported prescription drugs. Can you tell us what it would take to certify the safety of drugs that are made in America and reimported from other countries?

Answer. The practical problems associated with ensuring the safety and quality of drugs imported from foreign pharmacies and wholesalers are substantial, because FDA and state boards of pharmacy do not have authority over the drug distribution chain outside the U.S., nor does FDA have the ability to monitor and regulate the manufacture of drugs intended for markets other than the U.S.

Foreign pharmacies and wholesalers are not subject to FDA or state oversight, not licensed in the U.S., not subject to review or inspection by U.S. regulatory bodies, not required to meet U.S. standards for storage and safe handling of drug products, and not subject to U.S. penalties for failure to comply with Federal or state requirements. The drug distribution system as it exists today is a "closed" system. Most retail stores, hospitals, and other outlets obtain drugs either directly from the drug manufacturer or from a small number of large wholesalers. FDA and the states exercise oversight of every step within the chain of commercial distribution, thereby ensuring a high degree of product potency, purity, and quality.

Moving from the current "closed" distribution system with relatively few importers to an "open-border" distribution system would create opportunities for bringing prescription drug products into the country outside the system of safety and effectiveness monitoring overseen by FDA. It would increase the risk that counterfeit, misbranded, and adulterated drugs would show up on U.S. drug store shelves and in American homes.

With respect to manufacturing, FDA drug approvals are manufacturer-specific, product-specific, and they include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. The drugs must be produced in FDA inspected facilities. Drugs that are imported outside of this regulatory process bypass these protections, and no amount of visual inspection at U.S. borders can provide the same level assurance of safety, quality and effectiveness as FDA's drug approval process.

Last year, as part of the MMA, Congress included language authorizing a program of drug importation, but only if the Secretary of Health and Human Services could certify that implementation of the program would not compromise the safety of the U.S. prescription drug supply. At the same time, Congress directed the Secretary to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. In February 2004, the Secretary created an intergovernmental task force, chaired by Surgeon General Richard Carmona, to provide that analysis and offer findings on how to best address this issue in order to advance the public health.

The taskforce includes representatives from FDA, the Centers for Medicare and Medicaid Services, Customs and Border Protection, and the Drug Enforcement Administration. The panel has brought together a wide variety of stakeholders to discuss the risks, benefits and other key implications of importing drugs into the U.S.

As an integral part of the study process, the task force held a series of six stakeholder meetings to gather information and viewpoints from consumer groups, health care professionals, health care purchasers, industry representatives and international trade experts. A public docket for comments was opened as well. The task force is continuing its examination of these issues and working to complete its work as expeditiously as possible.

RESPONSES TO QUESTIONS FROM SENATOR LINCOLN

Question 1. While re-importing drugs from Canada is not a long-term solution to our problem, how can we say there is a safety issue with Canadian drugs when American companies' overseas facilities produce drugs with minimal FDA oversight and then ship them to the U.S.?

Answer. Overseas facilities that produce and ship drugs to the U.S. actually do so with substantial FDA oversight. To obtain FDA approval for any drug, the sponsor must comply with FDA's statutory and regulatory requirements in all respects, regardless of the country in which it is based or whether the manufacturing plant is located in the U.S. or abroad. FDA drug approvals are manufacturer-specific, product-specific, and they include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. FDA must inspect the facilities in which the drugs are produced. By contrast, drug products that are produced for the Canadian or other markets are not subject to FDA oversight.

Question 2. American drug makers are limiting supplies to Canadian pharmacies that sell to U.S. customers "out of concern that Canadian patients could face shortages." The question arises: why not just increase production, especially when the marginal cost is negligible?

Answer. This is an issue that the pharmaceutical companies, rather than FDA, would be able to address.

Thank you for your continuing interest in this important issue.



**Testimony of Senator Tim Johnson
Hearing on International Pharmaceutical Trade
Submitted to the Senate Finance Committee
April 27, 2004**

The United States remains the only developed country that does not protect its consumers from drug price discrimination, and as a result, American consumers continue to pay the highest prices in the world for prescription drugs. Drug spending in the U.S. and Canada rose by 11 percent last year to \$230 billion, which accounts for nearly half of all the worldwide sales. Among seniors in the U.S., total prescription drug spending rose an estimated 44 percent between 2000 and 2003. In 2002, a Families USA study found that for the 50 drugs most frequently used by seniors that year, prices rose 3.4 times the rate of inflation in 2002.

The House Committee on Government Reform report released last year found that seniors who lack drug coverage must pay twice as much for the five most popular drugs as purchasers in many foreign countries, those prices being 131 percent higher than in the U.K., 112 percent higher than in Canada, and 105 percent higher than in France. And for some drugs, U.S. seniors pay well over twice the price. For example, Zocor, a cholesterol medication costs only \$37 dollars in France for a monthly supply, but in the U.S. that drug will cost \$117 dollars—over three times as much. A month supply for Prevacid, an ulcer medication costs only \$42 dollars in the U.K., compared to \$118 dollars in our country.

Clearly this price discrimination must be addressed. Many, including myself had hoped that the Medicare drug bill would be the first step in tackling the skyrocketing costs of prescription drugs. Unfortunately, the final product did very little to address these concerns. The new law expressly prohibits the Secretary of the Department of Health and Human Services from negotiating lower drug prices. When I traveled to South Dakota earlier this year to discuss the Medicare bill, seniors back home found this fact quite disturbing. The new law also includes provisions that will allow the Secretary to prohibit real access to drug reimportation. Meanwhile, the cost estimates of the new prescription drug program continue to rise—to somewhere between \$500 and \$600 billion dollars over ten years.

We are in need of real solutions to this problem, and it was my hope that a real discussion could occur about drug pricing. Unfortunately, some Republicans in Congress are supporting tactics that will do nothing to address the costs of prescription drugs which are spiraling out of control. I was outraged to learn that some in this body, and in the House of Representatives are pushing a strategy that would require the U.S. Trade Representative or USTR to push other countries through trade agreements to increase their prescription drug prices. Most recently, House Speaker Hastert and others in Congress advocated that the USTR negotiate with Australia to increase its drug prices within its Pharmaceutical Benefits Scheme or PBS.

Such proposals are completely outrageous for several reasons. First, our government should not be telling another country how to run their health care system. How would this Administration feel if the Australians asked us to develop a universal health care program? Additionally, I find it inappropriate that some in Congress and the Administration would find it appropriate to ask other countries to increase their drug prices when we certainly wouldn't do the same for our citizens. Would we be willing to increase drug prices under the Veterans health program? Highly unlikely.

Now, some of our colleagues will say that other countries need to share the burden of research and development or R&D, and that in doing so we will help to reduce prices in the U.S. We should be very clear here. Any trade agreement proposals that would require another country to increase its prescription drug prices provides no guarantees that prices will go down for U.S. consumers. There is no data available to indicate that our prices would go down. In my mind, if this argument is the underlying justification for promoting these type of policies, the USTR, members of Congress supporting these plans, and the President owe it to our trade partners and American consumers to provide the data—the proof that American consumers will benefit from increasing prescription drug prices around the world.

I also think we need to be very careful when making the assumption that R&D is the cause of our higher prices in this country. Isn't it possible that the lions-share of the prices paid by American consumers is actually going into the back pockets of the pharmaceutical industry rather than to research and development? There are very few industries that can boast the type of sales claimed by the drug industry, which has enjoyed average annual sale increases of 10 percent in recent years. A Public Citizen June 2003 report found that in 2002, the top 10 drug companies had total profits of \$36 billion, and those profits registered were equal to more than half of profits netted by the entire list of Fortune 500 companies when all losses are subtracted from all gains. And while some may argue that this increased spending is justified because it reduces other costly health care spending, the overall rate of health care inflation continues to soar with no end in sight, making it more and more difficult for businesses and individuals to purchase health insurance coverage.

Beyond straight profits, the pharmaceutical industry continues to increase their spending on direct-to-consumer advertising and lobbying. One study found that eight major American pharmaceutical companies spent more than twice as much on marketing and administrative costs than on research and development. The Security and Exchange Commission's 2002 financial data finds that for the fiscal year ending in December of 2002, the average profits of Pfizer, Merck, Bristol-Myers Squibb, Abbott and Wyeth was \$5.1 billion, marketing and administration were \$5.2 billion and R&D was much less at \$2.3 billion. And let's not forget the campaign spending habits of the drug industry. During the 2000 election cycle, the drug industry gave disproportionate support to President George W. Bush and seventy percent of the industry's unprecedented \$24.4 million in campaign contributions was spent on Republicans.

With all this in mind, I find it very hard to believe that American consumers are carrying the research and development burden, rather than the stockholder profit burden. And given that drug companies spend more on TV ads, marketing and administration than they do on drug research, perhaps we should first ask why the domestic pharmaceutical industry won't spend more of its money on developing new drugs, before we start asking our trading partners to pay higher prices for drugs.

The outcome of the Australia trade agreement included requirements that the PBS program in that country provide more transparency in how decisions are made about covered drugs. The PBS system seems to me to be a very good system. Before a medicine can be subsidized by the Australian government, the Pharmaceutical Benefits Advisory Committee or PBAC must recommend that a drug be listed on the PBS. When deciding what drugs make the list, the PBAC takes into account the medical conditions for which the medicine has been approved for use, its clinical effectiveness, safety and cost-effectiveness compared to other treatments. A drug providing new benefits receives a higher price reflecting that advantage. This system rewards true innovation by the pharmaceutical industry while ensuring value for the taxpayer dollar.

This is a well thought out and scientific process and I think the U.S. should at least explore similar steps in order to reduce drug prices under the Medicare program. I also think that the clinical comparative effectiveness analyses that the PBAC conducts are something that we should be making a priority in our country. The U.S. should also establish an independent source of this type of information. Right now, one of the reasons drug costs are so high in the U.S. is because consumers, doctors and purchasers do not have access to objective, unbiased, reliable data to compare how drugs measure up to one another. This type of information would force drug companies to truly compete with one another based on the value of their products. Australia is on the right track here and we should follow suit.

With the help of Senator Conrad, I am pleased that I was able to obtain support during the Fiscal Year 2005 budget markup for a Sense of the Senate resolution supporting \$75 million for the Agency for Health Care Research and Quality or AHRQ for getting these types of studies started. Senators Frist, Clinton, myself and others will be sending a letter to the Labor-Health and Human Services-Education appropriations subcommittee asking for these funds in 2005. I hope that Senator Frist and his colleagues will take the steps necessary to see that this gets done. Having comparative effectiveness data available and accessible to physicians and their patients has the potential to reduce our nation's prescription drug expenditures, by enabling doctors to make better informed prescribing decisions.

I find it very interesting that the final language in the Australia Free Trade Agreement includes transparency provisions that will assist U.S. drug manufacturers in having opportunities to effect the PBS decision-making process, while these same companies refuse to provide transparency to the American people in how they set their market-entry prices for new drugs, what types of deals they offer their favored customers, and what type of rebate relationships they have with Pharmacy Benefit Managers. Surely U.S. purchasers deserve greater transparency as well.

It is astounding that the USTR, this Administration, and certain members of Congress are exerting so much effort to push policies that will increase the market power of drug companies by extending their monopolies in other countries. I question whether some of the tactics being proposed reach beyond what is called for by principal trade negotiating objectives. Ultimately, some of these proposals may even result in drug higher prices under the VA, DoD and other federal programs. I strongly object to these proposals and call on the Administration and members of Congress to provide the proof that these type of agreements would be effective in reducing prices in our country and will not negatively impact existing drug price arrangements for our programs.

Statement of Senator Kyl, Chairman of the Subcommittee on Health Care
Joint Hearing by Subcommittees on Health Care and International Trade
of the Senate Committee on Finance
“International Trade and Pharmaceuticals”

April 27, 2004

I want to thank Chairman Grassley for scheduling this joint subcommittee hearing. The Committee does not often have joint subcommittee hearings, but I believe the subject matter of this hearing, covering both health care and international trade issues, is uniquely suited to this format. I also thank the chairman of the Subcommittee on International Trade, Senator Thomas, for co-chairing this hearing with me today.

I was very pleased that our U.S. Trade Representative, Ambassador Zoellick, raised the issue of prescription drug pricing policies for the first time during negotiations of the recently concluded U.S.-Australia Free Trade Agreement and that he expects to raise it in future negotiations.

I have long thought that the prescription-drug price controls employed by foreign countries amount to an unfair trade practice because they block the access of U.S. products to foreign markets. Worse, perhaps, is that such price controls impose unacceptable burdens on U.S. citizens, who pay up to 60 percent more for prescription drugs, compared to citizens in countries that use price controls. In my opinion, the answer is not that the U.S. should adopt price controls—a solution

with tremendous downsides, which I hope today's hearing will explore—but that we should work with other countries to eliminate their price controls.

The primary reason to use trade negotiations to address foreign price controls on prescription drugs is the health and well-being of the American people and of people around the world. Because the United States is the only major country to allow market pricing for pharmaceuticals and medical devices, companies are forced to finance their research and development costs through prices charged to U.S. consumers. They simply cannot recoup their R&D costs in countries that impose price controls. The resulting cost-shift of the R&D burden to U.S. consumers is unfair.

Another result is that much of the pharmaceutical R&D has migrated from Europe, which had been the R&D leader, to the United States—we actually insource tens of thousands of research jobs in the industry from foreign-based companies. But while the jobs and the breakthrough therapies created are a tremendous benefit, American consumers cannot continue to finance medical R&D for the entire world.

As Dr. Mark McClellan, the former Commissioner of the Food and Drug Administration noted, “Everyone’s effort to get a free ride on new drugs will grind the global development of new drugs to a halt.” He said it is “unfair to Americans, who are bearing an increasing share of the burden, and cannot be expected to do so indefinitely.”

Americans have begun objecting to this unfairness. The wrong solution is to move toward price controls in this country. If Americans import price-controlled drugs from other countries, we are in effect adopting the price controls of other countries.

The long-term effects of such a policy could be devastating to future R&D breakthroughs. As *The Wall Street Journal* editorialized just yesterday, “The politicians and lobbyists in the U.S. who have been clamoring for drug-reimportation laws to lower the costs of prescription medicines would do well to look at the devastation price controls have brought to Europe’s drug industry.” Europe used to produce two-thirds of the new drugs, but now produces less than one-third—the shift all coming to the U.S., precisely because we don’t control prices here...yet.

It takes 10 to 15 years and costs more than \$800 million to do the research and testing to successfully bring a new medicine to patients. Only 250 of 5,000 screened compounds enter pre-clinical testing, and only one of five drugs that enter clinical trials is approved as a new medicine. Only three out of 10 marketed drugs produce revenues that match or exceed average R&D costs. If U.S. companies had to finance breakthrough drugs only with the prices that were set by governments, we could well see pharmaceutical companies scale back their R&D activities. Many companies have, for example, already reduced or even ended their research and production of antibiotics. We may find that other areas face similar threats as a result of price controls.

We must begin discussing the negative repercussions of price controls with our allies in the G-8 and the Organization of Economic Cooperation and Development. Our European allies have seen the flight of their drug companies’ R&D activities to America; they understand the effect price controls have had on their economies. They know that price controls inevitably lead to shortages—shortages in available drugs and a reduction in the development of new, innovative pharmaceuticals.

The world has not yet felt the full impact of price controls reducing the supply of drugs because the United States is making up much of the difference for others by paying the bulk of the world's R&D expenses. If we were to adopt price controls, either by allowing reimportation or by adopting actual price controls, the result for the future health of the world would be devastating.

I look forward to hearing the testimony of our two panels today as we begin exploring how the United States can address this very serious issue.

**Opening Statement
SFC Hearing on International Drug Pricing
Senator Jay Rockefeller
April 27, 2004**

Thank you Chairman Kyl and Chairman Thomas, and I'd like to thank all of the witnesses for what I expect will be interesting testimony today.

Prescription drugs are a critical part of modern medicine. However, access to these essential drugs is largely limited by the unsustainable increase in drug prices. Patients are sacrificing other basic necessities in order to afford their drugs, or worse yet, going without them altogether. This is particularly true of seniors who, as a group, are the largest consumers of prescription drugs.

The new Medicare prescription drug law will do little to help seniors with the high cost of drugs because of the meager benefit structure and the inability of Medicare to negotiate drug discounts. In fact, many seniors will end up paying more for prescription drugs than they did prior to the bill's enactment.

States are also spending a substantial portion of their annual budgets on prescription drugs – for Medicaid beneficiaries as well as for state employees. As the costs of prescription drugs continue to rise and states continue to face budget shortfalls, many states are looking to prescription drug reimportation as a way to ease their financial burdens. My home state of West Virginia is among them.

I am disappointed that this is the first hearing on prescription drug pricing since passage of the Medicare law, and we are using it to focus on trade policies that do not guarantee any savings will be passed onto American consumers. We cannot even guarantee that such policies will result in more research and development of new and innovative therapies.

In fact, we already know that much of the money U.S. drug companies attribute to research and development is actually spent on marketing. According to a 2001 Families USA report, U.S. drug companies that market the 50 most often prescribed drugs to seniors spent almost two-and-one-half times as much on marketing, advertising, and administration as they spent on research and development – that's \$45.4 billion on marketing, advertising, and administration and only \$19.1 billion on research and development.

Instead of focusing our efforts on trying to increase the prices paid by other countries, I think our time would be much better spent focusing on policies that we know have a direct impact on lowering prescription drug prices domestically. Allowing the reimportation of prescription drugs from other countries, permitting Medicare to negotiate directly with drug companies on behalf of seniors, and limiting direct-to-consumer advertising are all policies that we know will lower drug costs for American consumers.

I expect that we will hear much debate about these issues today, and I look forward to the testimony.

**Testimony of
Deputy U.S. Trade Representative Josette Sheeran Shiner
before the
Committee on Finance
Subcommittees on Health Care and International Trade
United States Senate
April 27, 2004**

Chairman Kyl, Chairman Thomas, Senator Baucus, Senator Rockefeller, and Members of the Committee, I welcome this opportunity to testify on international trade and U.S. pharmaceutical policy and to explain how our trade initiatives are promoting innovation and ensuring access to lifesaving medicines. I value the close cooperation I have had on trade issues with you and other Members of Congress and appreciate your leadership on this important and complex topic.

Trade Promotes Innovation

Innovation is vital to the success of many U.S. industry sectors – from pharmaceuticals and medical devices to telecommunications and information technology. Innovation within and across these and other sectors brings life-saving medicines and other revolutionary products to market, puts existing products to creative new uses, and even launches entirely novel industries. It means higher productivity, faster economic growth, and better living standards for American families.

Developing groundbreaking medicines and other innovative products depends largely on two factors – regulatory regimes that encourage the introduction of new products, and strong and effective intellectual property rights (IPR) protections and enforcement. Innovation thrives in the United States because of our fertile economic environment – an environment that encourages the flow of capital to the most productive uses and ensures that novel ideas are granted strong IPR protections. American pharmaceutical companies produce an estimated two-thirds of the world's innovative medicines.

America's trade policy is promoting innovation and creating new opportunities for innovative U.S. industries. The Office of the U.S. Trade Representative (USTR) has successfully led efforts to build a worldwide legal infrastructure that supports and rewards innovation. And we are working globally, regionally and bilaterally to counter barriers that restrict access to innovative health care products and discourage research and development (R&D) that can improve quality of life and, in many cases, save lives.

Building the Infrastructure for Innovation

Strong intellectual property rights (IPR) protections are the foundation for innovative R&D. These protections – including patents, copyrights or trademarks – provide vital incentives to invest in innovation. They ensure that pharmaceutical companies and other knowledge-based firms are

rewarded for their unique ideas and achievements.

USTR has been instrumental in bringing the strong IPR protections we enjoy at home to the trading nations of the world – fostering a global climate for groundbreaking innovation and research in the development of lifesaving medicines. IPR had been on the international economic agenda for decades when the United States joined other members of the General Agreement on Tariffs and Trade (GATT) to launch the Uruguay Round of global trade negotiations. By the time negotiations commenced on a multilateral Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1986, a large and growing consensus had emerged within the international community on the importance of IPR protection to economic growth and on fundamental rules for protecting new ideas and innovations. USTR seized the opportunity of those negotiations to harvest and bring together rules that had been negotiated in a number of intellectual property treaties – clarifying and improving them where necessary and making them subject to binding dispute settlement.

A decade after the conclusion of the Uruguay Round, TRIPS remains the basis for our ongoing efforts to improve the legal protection and enforcement of IPR around the world. USTR is vigilant in ensuring that our trading partners around the world live up to their TRIPS commitments – using our annual Special 301 Reports to identify and resolve the IPR concerns of U.S. pharmaceutical companies and many others in markets worldwide. We are instrumental in fighting the counterfeiting of patented drugs around the globe. These illegal copies not only steal protected patents, but prey on unsuspecting consumers with fake and often unsafe versions of critical medicines. Most recently, we have secured an agreement from China to crack down on such counterfeit trade and to introduce deterrent criminal penalties for violators. And we are raising the bar through our free trade agreements (FTAs) by crafting groundbreaking IPR provisions that build and improve on the TRIPS foundation.

Securing Access to Lifesaving Medicines

Through global, regional and bilateral trade negotiations, USTR is also knocking down barriers our pharmaceutical and other companies face in particular overseas markets – enabling them to access new customers, seek additional economic rewards of their innovations and deliver life-saving new medicines to the world. We are successfully opening new markets and resolving trade-related concerns regarding access to medicines.

Through the World Trade Organization (WTO), we are working globally to deliver expanded market access to U.S. pharmaceutical firms and other innovative industries. In successive rounds of multilateral trade negotiations, we have sharply lowered tariffs and non-tariff barriers around the world, to the benefit of U.S. companies, workers and consumers.

During the Uruguay Round, for example, the United States and 21 other major trading nations agreed to the reciprocal, immediate (from January 1, 1995) elimination of tariffs on existing pharmaceutical products and committed not to impose duties on new pharmaceutical products as they are developed. This initiative covered finished pharmaceutical products and chemical intermediates used in the

production of those products – giving consumers around the world better access to innovative drugs. We have already begun work on the third review of this agreement to ensure that duty-free treatment is guaranteed to new medicines – a top priority for U.S. industry.

The United States also led a successful effort in the WTO to resolve the crucial issue of drug patents and access to medicines, especially for pandemic diseases like HIV/AIDS, malaria and tuberculosis – striking a delicate balance between addressing the needs of the poorest countries while ensuring the strong IPR protections necessary to foster the future development of lifesaving drugs.

Regionally, the United States successfully removed barriers to trade with Canada and Mexico through the North American Free Trade Agreement (NAFTA). The NAFTA eliminated tariffs among the three countries on nearly all products, including pharmaceuticals.

Through completed and ongoing bilateral FTAs – including our recent agreement with Australia – the United States is:

- Advancing transparency provisions that provide for greater openness for government decision-making on drug approvals and reimbursements.
- Pursuing state-of-the-art IPR provisions that afford better protection for test data, extend patent terms to compensate for delays in granting the original patent, and help to prevent arbitrary patent revocation and the marketing of drugs that violate patents.
- Opening new markets to U.S. services and investment – giving American firms opportunities to provide supplemental health insurance and promote awareness of new medicines to consumers abroad.
- Eliminating costly customs duties on U.S. medicines exports worth hundreds of millions of dollars a year. Nearly all duties on U.S. pharmaceutical products were or will be eliminated immediately through our FTAs with Jordan, Chile, Australia and the Dominican Republic. Most pharmaceutical products will be duty-free immediately on implementation of FTAs with Morocco and Central America, with the remainder removed over a phase-in period.

These commitments are already bearing fruit in Singapore, where USTR and other agencies have successfully pressed that government to publish draft IPR legislation on patent linkage and parallel imports for public comment, citing FTA transparency provisions. Singapore posted the draft laws on the Internet on March 30, and U.S. agencies and other interested parties – including pharmaceutical companies – are currently reviewing them. We are seeking similar significant results in ongoing and planned negotiations with the Southern African Customs Union, Bahrain, Thailand, Panama and the Andean countries.

We are also advancing bilaterally through government-to-government consultations aimed at reducing barriers and improving market access for American medicines. Where we see trade

problems, we move to resolve them. And where we see trade barriers, we seek to eliminate them – from negotiations spanning the last ten years to our most recent work with China. For example:

- Over the past decade, USTR has pursued greater market access for U.S. and other foreign pharmaceuticals in Korea, which up until the late 1990s were not allowed to be marketed or sold under the Korean national healthcare system. In 1999, after consultations with the United States, Korea agreed to place foreign drugs on its national health insurance reimbursement list for the first time and to take a more market-based approach to drug pricing. Largely as a result, U.S. and other foreign firms have been able to grow their business in Korea significantly and now hold about 30 percent of the market.
- Pharmaceutical issues have been a centerpiece of our ongoing Regulatory Reform Initiative with Japan. Under this initiative, which I chair with Japan's Deputy Foreign Minister Fujisaki, we have worked with Japan on a range of pharmaceutical matters to uphold the principle of innovation, promote transparency, expedite product approvals, and take a fairer approach to drug pricing. Under the 1998 U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy, for example, Japan committed to two important principles: ensuring transparency by allowing foreign drug and devices manufacturers meaningful opportunities to input into the development of Japan's healthcare policies; and further speeding the introduction of innovative new pharmaceuticals by significantly shortening approval times. We have also pushed back discriminatory pricing initiatives in Japan that targeted U.S. medical devices.
- I have been actively engaged in efforts to urge China to end the rampant counterfeiting of U.S. pharmaceuticals and many other products that harm American manufacturers and put health and safety at risk, to price innovative drugs fairly, and to add new drugs to its national formulary, which controls access to medicines for China's nearly 1.3 billion people and currently contains no medicines produced after 1998. In discussions last week between U.S. Trade Representative Robert Zoellick and China's new Commerce Minister Bo Xilai, China agreed to delay onerous new pricing decisions planned for certain innovative drugs and to update its national formulary. At a subsequent meeting of the U.S.-China Joint Commission on Commerce and Trade (JCCT), China also committed to a range of improvements to its IPR enforcement regime aimed at substantially reducing IPR infringement levels. Those commitments included: applying criminal sanctions to a greater range of IPR violations – from on-line piracy to the import, export, storage and distribution of pirated and counterfeit goods; conducting nation-wide enforcement actions against piracy and counterfeiting; launching a national campaign to educate its citizens about the importance of IPR protection; and establishing a U.S.-China IPR working to consult and cooperate on IPR matters. These commitments are significant and should pave the way for successful high-level discussions on the economic aspects of healthcare delivery in Beijing at the end of next month.
- Closer to home, we secured a commitment from Canada to phase out its “compulsory licensing” system that required U.S. companies to license their proprietary medicines to

Canadian firms. Laws implementing that commitment took effect in February 1993.

- And in Mexico, we resolved U.S. pharmaceutical company concerns over government procurement of generic versions of patented pharmaceuticals and decisions by the Mexican Ministry of Health to grant health registrations to generic products without verifying whether a patent already exists for those products.

Meeting New Objectives

Trade Promotion Authority (TPA) granted by Congress in the Trade Act of 2002 introduced a new trade negotiating objective – requiring the Administration to seek to address price controls and referencing pricing systems maintained by foreign governments that discriminate against American products, including pharmaceuticals.

USTR pursued that objective in trade negotiations with Australia, and I and others at USTR worked closely with this Committee to make the U.S.-Australia FTA the first to include special provisions addressing market access for pharmaceuticals. In the agreement, the United States and Australia committed to common principles on facilitating high quality health care and continued improvements in public health for their nationals. These principles include recognition of:

- The important role innovative pharmaceuticals play in delivering high quality health care;
- The importance of research and development in the pharmaceutical industry, and of government support for R&D – including through IPR protection;
- The need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures; and
- The need to recognize the value of innovative pharmaceuticals through adopting and maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.

To address these principles, Australia will make a number of improvements to its Pharmaceuticals Benefits Scheme (PBS) procedures that will enhance transparency and accountability in the operation of the PBS – including establishing an independent process to review available determinations for product listings. Crucially, the FTA also establishes a Medicines Working Group that will provide a forum for ongoing dialogue on Australia's system of comparing generics to innovative medicines and other emerging health care policy issues. In addition, the U.S. Food and Drug Administration and the Australia Therapeutic Goods Administration will work together to make innovative medical products available more quickly. We urge Congress to act quickly to approve the U.S.-Australia FTA, so that we may begin implementing agreed provisions and working toward further reform.

Our negotiations with Australia and our ongoing consultations with this Committee and others in Congress following the granting of Trade Promotion Authority have placed new barriers to innovation and access to medicines squarely on our agenda, and we are acting to gather the information we need to understand how these barriers operate in different markets around the world and to effectively organize our trade negotiating team to address them.

The study on drug pricing practices required under the Medicare Prescription Drug Improvement and Modernization Act of 2003 will aid in our understanding. In this study, Congress asked the Department of Commerce – in consultation with USTR, the U.S. International Trade Commission and the Department of Health and Human Services – to report on drug pricing practices of countries that are members of the Organization for Economic Cooperation and Development (OECD) and whether those practices utilize non-tariff barriers with respect to trade in pharmaceuticals.

To bring greater focus to our work in this important area, Ambassador Zoellick also recently announced the creation of a new Assistant USTR for Pharmaceutical Policy. Ralph Ives – the Assistant USTR for Southeast Asia who served as lead negotiator for our FTA with Australia – will serve in this capacity, bringing 30 years of trade policy expertise to the job. He will be assisted by Deputy Assistant USTR for Southeast Asia Barbara Weisel, who also gained experience through the U.S.-Australia FTA negotiations. This announcement recognizes that the trade challenges facing pharmaceuticals firms – like so many others – cut across a number of key functional and geographic areas – from tariffs and non-tariff barriers to IPR and services, and from Asia and Australia to Europe and North America.

Conclusion

Mr. Chairman, promoting innovation in the pharmaceuticals sector and ensuring access to lifesaving medicines has been on the U.S. trade agenda for many years. And we have established a solid track record of delivering results for this important sector and for the workers and consumers who contribute to and benefit from its achievements.

But we are here today to consider new concerns and new objectives. I believe the U.S.-Australia FTA developed core principles that may serve as useful guideposts as we consider the best opportunities and methods to address barriers to trade in pharmaceuticals and the objectives that will steer us in ongoing and future global, regional and bilateral negotiations – including upcoming FTA negotiations and consultations with Canada and other major trading partners bilaterally and in international fora like the OECD. Our experience with Australia has also taught us that we need to take a customized approach to tackling these barriers – recognizing that healthcare systems and restrictions on trade in medicines differ significantly from country to country.

As we move forward, we welcome the continued guidance and leadership of this Committee and others in Congress.

Thank you.

Responses to Addition Questions for the Record

**U.S. Senate Committee on Finance
Joint Subcommittee Hearing**

**“International Trade and Pharmaceuticals”
April 27, 2004**

Questions from Senator Lincoln to Deputy U.S. Trade Representative Shiner

1. Is there any evidence that prices in countries like Canada and Australia (who use their governments to negotiate prices) are lower than what the private sector in the United States can negotiate?

Response 1:

There are many factors that determine pharmaceutical prices in different markets, including government policies and income differentials. There is evidence that pharmaceutical prices are lower in some countries than in the United States, however, estimates of the price differences vary considerably based on the methodology used. The Department of Commerce, in consultation with USTR, HHS and the ITC, is conducting a study on drug pricing practices in OECD countries, as directed in the Medicare Conference report. We expect to be in a better position to try to answer this question after the Department of Commerce completes its study.

2. The international market for pharmaceuticals and the determination of prices across countries in the global market are influenced by a number of factors. One key factor is the large cost of R&D, which is global in nature. R&D expenditures remain the same regardless of how many consumers or countries are served by the product. Because these costs cannot be easily attributed to any particular consumer or country, the pharmaceutical industry faces the problem of how to assign costs to the different countries they serve. What can we do about this? Should we enter into a discussion with countries with high R&D expenditures to make drug prices more equitable or work together to reduce costs and provide incentives for developing new medicines? Do we need new global accounting methods to assign costs?

Response 2:

R&D is vital to the development of innovative new medicines that can improve the quality of life and save lives. Developing groundbreaking medicines and other innovative products depends largely on a number of factors including regulatory regimes that encourage the introduction of new products, strong intellectual property rights protections and enforcement as well as private sector and government support for R&D.

We share your concern that global research and development may be disadvantaged by disincentives in some nations. We have designated an Assistant U.S. Trade Representative to be responsible for pharmaceutical policy at USTR to explore the trade related aspects of your concerns. We have addressed these topics with numerous governments, including Australia, China, Japan and Canada.

In addition, the Medicare Conference report directs USTR and the Departments of Commerce and HHS to “analyze whether bilateral or multilateral trade or other negotiations present an opportunity to address these price controls and other such practices and shall develop a strategy to address such issues in appropriate negotiations.” We are currently considering the most appropriate approach for addressing these issues. A dialogue with countries on pharmaceutical R&D, including how to provide incentives for the development of new medicines, is being considered.

3. Will reducing international barriers and pursuing market access for pharmaceuticals result in lower prices for U.S. consumers? Will it help the private insurance companies in the U.S. negotiate lower prices?

Response 3:

We are currently working with Congress to explore ways to reduce the research and development burden on American consumers, and to assess to what extent Americas share a disproportionate share. The Department of Commerce study, directed by the Medicare conference report, should help us assess the impact of drug pricing policies in other OECD countries. Competition in the U.S. market generated by the new Medicare cards program already has resulted in reductions off retail prices for both brand-name and generic drugs.

4. How will trade agreements that provide more market access to the U.S. pharmaceutical industry impact the VA National Formulary, the Medicaid Supplemental Rebate Program, and future attempts to enable Medicare to get the best prices for drugs?

Response 4:

USTR works closely with the VA, DOD, HHS, FDA and other relevant agencies to ensure that U.S. trade agreements do not require any changes to U.S. health care programs. The Pharmaceutical Annex to our FTA with Australia, for example, specifically excludes government procurement of pharmaceutical products, including pharmaceutical formulary development and management for federal healthcare agencies. Programs that are implemented at the state level, such as Medicaid programs, are not covered by the Pharmaceutical Annex.

U.S. agencies already comply with the requirements of the Government Procurement Chapter of the Australia FTA because the United States is a party to the WTO Government Procurement Agreement. However, since Australia is not a signatory to the WTO GPA, the FTA opens new opportunities to both Australian and U.S. firms.

5. Although many consider pharmaceuticals to be a cost effective tool to treat and, in some cases, reduce the disabling effects of many health conditions, as well as possibly reducing the need for hospitalization, many countries are increasingly seeking ways to contain costs related to national consumption of pharmaceuticals. What are we doing in the United States in this regard?

Response 5:

The response to this question can best be provided by HHS.

6. A recent report from the Institute of Medicine reveals that the VA National Formulary is not more overly restrictive “than other public or private formularies.” It also “rarely designates drugs or drug classes as absolutely excluded or requires prior authorization of drugs as managed care formulary systems frequently do, nor does it impose tiered co-payments as is often the practice in managed care.” Also, only 0.4 percent of veteran complaints could be attributed to the VA Formulary. Do you know how citizens in other countries such as Australia feel about their national health system’s pricing system? Do they feel that it is fair in ensuring access to medically-necessary drugs?

Response 6:

It is our understanding that Australians support the national health care system. However, there are reports that indicate views in Australia differ about the process for listing and pricing new drugs on the Pharmaceutical Benefits Scheme formulary and its impact on the ability of Australian citizens to gain timely access to the most innovative and “medically-necessary” drugs.

7. My understanding of the Australian reference pricing system is that if a drug is truly innovative, it will be paid for appropriately. How does the Australian reference pricing system ensure that patients have access to innovative drugs?

Response 7:

The Australian Government uses a reference pricing system to control the cost of pharmaceuticals it covers under its Pharmaceutical Benefits Scheme (PBS). While there is no annual budget limitation on PBS expenditures, Australian government officials acknowledge that the expected annual cost of each new drug is a factor in determining PBS listings. Indeed, Australian government studies have raised concerns about the availability of new drugs or new applications of drugs already on the PBS and have suggested alternative ways of increasing availability of new drugs to Australian patients.

Questions from Senator Kyl to Deputy U.S. Trade Representative Shiner

1. The Medicare Modernization Act call on the USTR, working with other government agencies, to develop a strategy for negotiating on price controls (recognizing that a one-size-fits-all strategy is not appropriate). Who is overseeing the day-to-day development of

that strategy and how is it going?

Response 1:

USTR is currently consulting with government, Congressional, industry, and academic experts and other stakeholders to develop a strategy for addressing barriers to trade in pharmaceuticals. We believe the principles established in the Australia FTA – namely the important role innovative pharmaceuticals play in delivering high quality health care; the importance of research and development in the pharmaceutical industry, and of government support for R&D, including through IPR protection; the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures; and the need to recognize the value of innovative pharmaceuticals through adopting and maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical – provide a foundation for moving forward. Ralph Ives, a veteran USTR negotiator, has been named Assistant USTR for Pharmaceutical Policy in addition to serving as Assistant USTR for Southeast Asia and the Pacific. Mr. Ives and his deputy, Barbara Weisel, will be overseeing the day-to-day strategy on pharmaceutical issues under the direction of USTR Ambassador Zoellick and Deputy USTR Ambassador Shiner.

2. I understand that Germany is making some troubling changes regarding pharmaceutical market access, including mandatory 16 percent rebate and will possibly reinstitute reference pricing. Does USTR plan to engage Germany on these issues before they fully develop and initiate these measures?

Response 2:

We share your concerns regarding reported changes to Germany's pharmaceutical reimbursement program. We plan to discuss pharmaceutical market access issues with our German colleagues soon.

Questions from Senator Rockefeller to Deputy U.S. Trade Representative Shiner

1. It is my understanding that the recent trade negotiations between the U.S. and Australia were unexpectedly difficult because of the negotiations regarding Australia's Pharmaceutical Benefits Scheme. How have international pharmaceutical access and pricing issues been dealt with in previous free trade agreements? Why was this negotiation so different? What were the reasons behind USTR's decision to press Australia to make their procedures for selecting eligible drugs more transparent and to make the benefits of innovative drugs a factor in determining which brands will be subsidized?

Response 1:

USTR has dealt with market access issues related to pharmaceutical products through global, regional, and bilateral trade negotiations for many years. In previous FTAs, we have negotiated the elimination of duties on U.S. pharmaceutical products and strong IPR provisions relating to pharmaceuticals. Over the past few decades, market access and pricing issues also have been part of our trade dialogues with Canada, Japan and Korea and, more recently with China. Based

on new guidance from Congress, the Australia FTA was the first FTA that includes specific non-tariff market access provisions relating to pharmaceuticals. We pursued these pharmaceutical issues in the Australia FTA negotiations based on the objectives Congress set in the Trade Act of 2002, which are: "(A) to achieve increased transparency and opportunity for the participation of affected parties in the development of regulations; (B) to require that proposed regulations be based on sound science, cost-benefit analysis, risk assessment, or other objective evidence; (C) to establish consultative mechanisms among parties to trade agreements to promote increased transparency in developing guidelines, rules, regulations, and laws for government procurement and other regulatory regimes; and (D) to achieve the elimination of government measures such as price controls or reference pricing, which deny full market access for United States products."

We sought greater transparency in Australia's process for listing new pharmaceuticals because increased transparency is a key goal in our trade negotiations, especially when government processes are particularly opaque. As the Australian Government's own studies have shown, measures to enhance transparency and accountability of the Pharmaceutical Benefits Scheme (PBS) process are warranted. The PBS already has a process for determining which drugs will be subsidized. What the United States sought in the FTA negotiations was a recognition by Australia of the value of innovative pharmaceuticals as part of this process. Recognizing innovation was among the common principles to which the United States and Australia committed in order to facilitate high quality health care and continued improvements in public health for their citizens.

2. USTR recently appointed a U.S. Trade Representative for Pharmaceutical Policy. Are there similar positions for other goods – like agriculture and steel – that are typically part of trade negotiations?

Response 2:

USTR recently appointed Ralph Ives, Assistant USTR for Southeast Asia and the Pacific, also to serve as Assistant USTR for pharmaceutical policy, given his experience in negotiating Australia FTA provisions for pharmaceuticals. USTR has a chief negotiator for Agriculture, which is an ambassadorial position, as well as a chief textiles negotiator. In addition, we have specialists at USTR focused on telecommunications, autos, and other sectors. Previous USTRs have appointed special negotiators for specific issues, such as steel. The pharmaceutical issue, like these issues, cuts across a number of areas in USTR – industry, IPR, services, most regions – so Ambassador Zoellick thought it best to appoint someone who could focus USTR's overall work in the development of pharmaceutical trade policies.

Questions from Senator Bob Graham to Deputy U.S. Trade Representative Shiner

1. The March 1, 2004 Draft of Annex 2-C of the Australia Free Trade Agreement covers pharmaceuticals. The document applies to federal healthcare programs in that it includes the terms "federal healthcare authorities", "federal healthcare programs", and "federal healthcare agencies. I would like clarification as to whether there are any existing or

future U.S. programs that could be subject to the Annex. Please clarify for me which, if any U.S. agencies or programs that provide or arrange for coverage of prescription drugs (including, but not limited to Medicare, Medicaid, VA, DOD, or any state operated pharmaceutical assistance program) would be exempted from the Annex through the footnote relating to procurement and which would be subject to the Annex. For example, the Medicare program currently covers many drugs under Part B of the program. The Medicare program determines which drugs are covered, and the reimbursement level, but does not actually procure the drugs. It seems to me that Medicare's decisions regarding Part B drugs would thus be subject to the Annex. Is that correct? I would like an answer that responds specifically to each of the federal programs providing or reimbursing for pharmaceuticals, directly or indirectly, as well as for state programs that are wholly state financed and operated and those that are partially federally financed. Please reference the specific language in the draft agreement that clarifies which policy – the annex or the procurement chapter – applies to which agencies, programs, or activities.

Could any future U.S. federal program that uses federal ceiling prices, Federal Supply Schedule pricing requirements, or any federally-determined reimbursement system, or any state pharmaceutical assistance program including those that are partially financed through federal dollars be subject to the Annex? Please respond to this question both in terms of programs that would have the federal government actually taking ownership of the drugs, as well as any program in which the federal government wholly or partially made payment for the drugs, but did not actually possess the drugs at any time.

Response 1:

USTR works closely with all relevant agencies to ensure the FTA does not require any changes to their health care programs. Procurement of pharmaceutical products by VA and DoD is excluded from operation of the Annex by footnote 1. Procurement of pharmaceutical products by state Medicaid agencies is excluded from the operation of the Annex because coverage and reimbursement decisions are made by state officials, not by Federal health authorities. The transparency obligations included in the Annex may apply to certain reimbursement decisions concerning pharmaceuticals under Part B, and current Medicare practice is consistent with the Annex. As it has been established, Medicare, Part D, which will take effect in 2006, will not be covered by the Annex since coverage and payment decisions are not directly made by the Federal health authorities.

The applicability of the transparency obligations in the Annex to future programs would depend on how they were structured. If the Federal government procured the drugs, the Annex would not apply (footnote 1). If private parties or state officials made the coverage and payment decisions, the Annex would not apply. Federal matching payments to a state for the purchase of a pharmaceutical product does not render the Annex applicable.

2. Please clarify the terms “pharmaceutical formulary development and management” (which appear to be subject to Chapter 15) versus “decisions regarding payment and coverage” or “procedures for listing of new pharmaceuticals or indications or for setting

the amount of reimbursement for pharmaceuticals" (which appears to be subject to Annex 2-C).

Response 2:

The Annex and accompanying documents do not contain a definition of the terms referred to. However, the development of a formulary is generally a part of the decisions relating to the listing of pharmaceuticals or indications for reimbursement purposes. Formulary management also would include promulgating and implementing usage guidelines, negotiating contracts and incentive agreements, actively managing utilization, and other related activities.

3. Could Annex 2-C be interpreted to apply when VA uses the formulary to make decisions regarding payment and coverage, even though actual management and development of the formulary would be subject to Chapter 15 and not Annex 2-C?

Response 3:

When the VA uses a formulary to make decisions regarding payment and coverage, this is considered to be part of government procurement by the first sentence of footnote 1 and thus excluded from the operation of the Annex, but subject to Chapter 15 on Government Procurement.

Question from Chairman Charles E. Grassley to Deputy U.S. Trade Representative Shiner

1. I was disturbed by a recent article published in the April 27th edition of The Washington Post in which it was alleged that the Administration has not been effectively enforcing international trade agreements. As Chairman of the Finance Committee I am deeply concerned about effective enforcement of our international trade agreements.

I have attached the article, along with the report and speech upon which the article is based, for your review. Is the article and the material upon which it is based accurate? If not, please describe which aspects of these materials are inaccurate. Also, please outline what steps the Administration has taken and is taking to effectively enforce our international trade agreements.

Response 1:

The United States Government's enforcement of existing trade agreements is no less important than producing new ones. Indeed, enforcement is inherently connected to the process of negotiating new agreements. Without determined enforcement, new agreements will serve as a source of disappointment and frustration instead of an opportunity to create new jobs for workers and new opportunities for business. We need to assure the American public, and forewarn our trading partners, that we are determined to use all available resources and remedies to combat unfair trade practices and secure a level playing field for American workers, farmers and businesses.

Virtually everything USTR does is connected with enforcement in some way. Negotiations to open markets and enforcement are two sides of the same coin. And the tools of enforcement involve far more than filing and winning cases in the WTO and other fora.

USTR seeks non-litigation solutions to trade disputes before launching official dispute resolution that can take nearly two years to conclude. As a result, we use our influence every day in any number of ways to open foreign markets and ensure fair treatment for products of America's workers and businesses.

We are interested in whatever available tool produces results. Sometimes we can persuade countries that a barrier hurts them, for example by raising the cost of food for families by keeping out beef or poultry. On other occasions, we need to explain -- often through technical discussions -- that an action by another ministry or their legislature violates the rules. Another tool is to build local support to press our foreign counterparts -- for example on the need to protect intellectual property, deregulate, or take other steps to lower costs and compel protected interests to face competition. Frequently, we use incentives creatively: We are resolving many disputes on investment, IPR, customs red tape, workers' rights, and a host of market access barriers as preliminaries to our initiation of free trade agreement negotiations. Furthermore, some countries are interested in better enforcement of trade, labor, and environmental rules but lack the technical capabilities or staff in complex areas such as IPR and sanitary and phytosanitary standards for farm products; therefore, we seek to match assistance to problem-solving, working with AID, USDA, international institutions, and the private sector -- both businesses and NGOs.

Of course, we also deploy disincentives -- whether through a "Special 301" list of IPR barriers, withdrawing preferential trade benefits, or other actions, often working with Congress. And then we have international litigation -- and the threat of it -- in the WTO or our expanding number of FTAs, which adds to our leverage. After we win a case, our goal remains to fix the problem, not just retaliate against others' exports to us; therefore, litigation is often a prelude to negotiation to resolve the dispute. To be most effective, USTR works with others to try to fit the right tools to the particular problem at the appropriate time, recognizing different circumstances call for different tools.

You can be assured that the bread-and-butter work of USTR, day-in and day-out, is to open -- and keep open -- markets for Americans, deploying the full range of enforcement tools as needed. We are continually building coalitions of allies -- with other countries, our private sector, with the private sectors of other countries, even with different ministries within another country -- to solve problems for American business, workers, and farmers. From time to time we need to make our case loudly and publicly. Much more often, our enforcement successes are quiet victories known only to governments and interested parties. Each tool is important. And they are each interconnected. It is our ability to have a full toolbox that produces the best results.

Thanks to the support of Congress, we are currently expanding our work in the enforcement area

-- with a particular focus on China. With our current appropriation, we are:

- Expanding the number of China negotiators in our North Asia office by 100 percent, enabling us to dedicate specialists to resolving issues of concern to U.S. businesses and workers, such as industrial policies that promote domestic industries unfairly, piracy of intellectual property, unscientific quarantine measures, and other trade barriers disguised as technical standards. We will also be able to widen our geographic focus in order to address WTO implementation concerns that arise outside Beijing at the regional and local level.
- Increasing the number of front-line attorneys in our General Counsel's office by 20 percent -- which will help prepare the groundwork for additional cases, and more importantly provide negotiators the ammunition to solve trade rule violations before litigation becomes necessary.
- Adding staff to our Office of Industry to ensure that we are adequately covering the manufacturing economy and following such key industries as paper, plastics, medical devices, machinery, machine tools, scientific instruments, fisheries, autos, commercial space launch, and others.
- Adding staff dedicated to strengthening China's intellectual property practices. China's lack of enforcement of intellectual property rights undermines U.S. commercial rights and the continued development of knowledge industries in the U.S. and abroad.
- Appointing a professional in our Geneva office to focus on China in order to enhance our litigation capabilities and expand our coordination with other WTO members on China WTO implementation issues.

We are increasing the resources we devote to researching Chinese laws and regulations, as well as systematically collecting information on IP violations -- information that can then become the basis either for bilateral negotiations or formal dispute settlement.

We have also, in the last year, with the support of the Small Business Administration, added an Office of Small Business Liaison to expand our outreach to small- and medium-sized businesses. The office is focusing on difficult markets, such as China, that America's small businesses find hardest to penetrate.

In addition to China, we are increasing our attention to India with the recent establishment of a separate office on South Asia Affairs.

Our colleagues at the State Department, Commerce Department, Treasury, USDA, and other agencies in the executive branch play a critical role in helping the Administration resolve disputes.

As you know, USTR's work on China -- as well as countries around the globe -- is done in close conjunction with other departments across the U.S. government, our 32 formal private sector advisory groups encompassing more than 750 individuals, our networks with private sector associations, businesses, and NGOs, and of course the U.S. Congress. Indeed, when Congress created the Special Trade Representative in 1961, it relied on the logic of a "networked" organization long before that concept became widely employed. Given the range of problems USTR addresses, we need to rely on the expertise, insight, and support of many others. Yet the logic of central coordination and integration in the Executive Office of the President enables us to be more focused, flexible, dynamic, and efficient. Indeed, over the past few years, a number of countries have been examining the USTR model as a way of sharpening their own capabilities.

United States Senate

WASHINGTON, DC 20510-5003

Statement of Senator Craig Thomas, Chairman
Subcommittee on International Trade
Senate Finance Committee

“International Trade and Pharmaceuticals”

April 27, 2004

The United States has embarked upon an aggressive trade strategy to open world markets to U.S. goods. To be successful, the United States needs to negotiate agreements that eliminate barriers, create transparency and level the playing field for domestic companies doing business abroad. Whether it is an automobile manufacturer, an agriculture producer, or a soda ash processor, opening up the world for U.S. business must remain a top priority for our trade negotiators.

We will hear testimony from two outstanding panels regarding international trade and the impact on the U.S. pharmaceutical industry. I believe this is one of the first such hearings in the Senate, but doubt it will be the last. The topic has broad implications for nearly every American and I'm pleased that we are taking a look at the issue today.

It is no secret we pay the highest prices for name brand prescription drugs in the world. There is also wide acknowledgement that the U.S. industry faces significant trade barriers around the globe that inhibit their ability to operate in an open and fair market. Many countries have erected trade barriers through the use of government-set price controls, volume restrictions, reference pricing, and decision-making processes that are often non-transparent. In addition, lax enforcement of intellectual property rights contributes to the trade difficulties the industry encounters. These practices limit market access and artificially reduce the number of consumers in the marketplace.

There are a variety of explanations for the current state of affairs. Virtually every other developed country has some form of socialized medicine where the government establishes drug

prices and controls the market. Regulations rarely allow a price to be set that reflects the actual cost of production and generally prohibits the recovery of a company's research and development investment. This framework developed over time and has remained virtually unchecked for decades.

With passage of the Trade Act of 2002, however, the situation changed. Through this legislation, Congress established as one of its primary trade objectives tighter regulatory practices to ensure that 1) government regulations and practices achieve increased transparency; 2) proposed regulations be based on objective evidence; 3) consultative mechanisms are established to promote transparent rule-making processes; and 4) government measures such as price controls and reference pricing which deny full market access for products from the United States are eliminated.

As we know, the issue of regulatory practices related to pharmaceuticals was one of the last items to be resolved in the recently completed Australia Free Trade Agreement negotiations. It is a sensitive issue for the folks in Australia and I respect their concerns. But it is an issue that deserved to be on the table and one that needs to be raised in future negotiations.

I look forward to hearing more regarding the Australia negotiations and how the Administration will address the Trade Act of 2002 objective on regulatory practices in the future. In addition, I welcome witness comments on how negotiations on this issue down the road will impact the drug industry and consumers around the world, including in the United States. Identifying the objective is easy. Achieving the objective is the challenge.

While the focus of today's hearing is on international trade policy, I do want to say a few things about a prescription drug issue that has been talked about a lot recently – importation. I understand the political urgency behind the recent introduction of importation legislation. It is frustrating to listen to the struggles of constituents who cannot afford their medications and not be able to offer a lot of solutions. However, the Senate is supposed to be a deliberative and thoughtful body and I am concerned in our hurry to address the situation we have not evaluated all the implications of legalizing prescription drug importation.

As mandated by the Medicare Modernization Act, Secretary Thompson appointed a task force to examine the issue and make recommendations by December 2004 on how to safely import drugs. The task force has already held several public meetings that have highlighted an issue often overlooked -- the generic drug industry.

Today FDA-approved generics account for more than 51 percent of all prescriptions filled in the United States. Generics depend on a competitive market place and innovation for their business. The generic industry has testified before the task force and has submitted written testimony for today's hearing sharing their concerns that a nationwide drug importation program could adversely affect them. Consumers would have little or no incentive to utilize the domestically manufactured less expensive version of a brand name drug. This would clearly impact the entire industry, jeopardizing a safe and affordable alternative for consumers.

There exist legitimate safety concerns about importation that must be addressed to insure our nation is not subjected to undue risk. We need to take a serious look at our current health care infrastructure and system and start making some tough choices. I believe information gathered at today's hearing will help move forward the process of mapping out a plan to make prescription drugs affordable and safe for all Americans.

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**JOINT FINANCE TRADE AND HEALTH SUBCOMMITTEES HEARING
INTERNATIONAL TRADE AND PHARMACEUTICALS**

April 27, 2004

TESTIMONY

SUBMITTED FOR THE RECORD

BY

THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (AdvaMed)

Bringing innovation to patient care worldwide

AdvaMed represents over 1100 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, our members manufacture nearly 90 percent of the \$75 billion in life-enhancing health care technology products purchased annually in the United States, and nearly 50 percent of the \$175 billion in medical technology products purchased globally. Exports in medical devices and diagnostics totaled \$22.4 billion in 2003, but imports have increased to \$22 billion - indicating a new trend towards a negative trade balance for the first time in over 15 years.

The medical technology industry is fueled by intensive competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Accordingly, our US industry succeeds most in fair, transparent global markets where products can be adopted on their merits.

Technology Solutions for a Changing World

Innovative medical technologies offer important solutions for industrialized nations, including Japan and European Union members that face serious health care budget constraints and the demands of aging populations. As these countries' patient populations age, healthcare systems are faced with potentially higher long-term costs with a smaller financially contributing workforce. Accordingly, reducing disability and the need for intensive long-term care are paramount goals for many countries. Advanced medical technology has a critical role to play in helping to facilitate care and minimize disability, and can actually help lower health care costs, improve the efficiency of the health care delivery system, and improve productivity by allowing people to return to work sooner.

To deliver this value to patients, our industry invests heavily in research and development (R&D), and US industry is a global leader in medical technology R&D. The level of R&D spending in the medical device and diagnostics industry, as a percentage of its sales, more than doubled during the 1990s, increasing from 5.4% in 1990, to 8.4% in 1995, to 12.9% in 1998. In absolute terms, R&D spending has increased 20% on a cumulative annual basis since 1990. This level of spending is on par with spending by the pharmaceutical industry and more than three times the overall US average.

However, when regulatory policies and payment systems for medical technology are complex, bureaucratic, non-transparent, or overly burdensome, they can significantly delay or deny patient access to the latest, state-of-the-art innovations. They can also serve as non-tariff barriers, preventing U.S. products from reaching patients in need of innovative health care treatments.

Pricing Trends that Constrain Innovation and Discriminate Against US Firms

Foreign governments employ a range of different mechanisms to pay for medical technologies and to set medical technology reimbursement levels. Relatively few countries employ free market mechanisms to establish medical technology reimbursement. In France, for example, a two-part review process establishes prices on a fee schedule for private hospital use of medical technologies, but as part of this process the French Health Ministry also establishes what it believes is the fair market price as well as target volume limits for the product.¹ Most recently, France has conducted a survey of other European markets to help inform this process of setting market prices.

This type of approach of price-setting for new technologies artificially sets prices for products and controls the market uptake of a product – leaving a centralized government authority to artificially restrict the clinical demand for a new technology. Price controls hinder fair market access between the U.S. and its trading partners and reduce the amount of trade in the economy. Price controls often fail to acknowledge the costs of research and development for the technologies, making countries without price controls shoulder the burden of paying for the development of these lifesaving and life-enhancing innovations. In addition, the problems in one country are further compounded when nations seek to borrow reference prices from other countries – thus transferring such artificial prices into a completely new market, with different market costs and patient populations.

Reference pricing is also an inappropriate way to establish reimbursement because of the fact that medical technology products are rarely identical from one country to the next. The envelope of available products in a single category inevitably includes obsolete models or products unique to that market. Even a single manufacturer may sell multiple different configurations, sizes and models of the same product that are not available in other countries, in order to meet demands of local purchasers.

In addition, differences in regulatory systems can mean that products are not always available in different markets in the same time frames. Innovator firms tend to seek first the markets that can assure a level regulatory playing field with minimal bureaucratic red tape. While market competition has been shown to drive down medical technology prices, even for breakthrough products, US companies do best when they can be based on quality and performance of their products.

Foreign Reference Pricing in Japan

After the U.S., Japan is the largest global market for medical technologies at \$25 billion. US manufacturers annually export over \$2.5 billion to Japan and dominate the markets for higher-cost implantable products as well as in vitro diagnostic products. These efforts have helped to grow and sustain a favorable US trade balance for medical devices in the range of \$1.1 billion in recent years. These statistics are good indicators of our industry's global

¹ The French Health Safety Agency's (AFSSAPS) Healthcare Products and Services Evaluation Commission (CEPP) determines whether a product is worthy of reimbursement and will provide a medical benefit rating. The Healthcare Products Economic Committee (CEPS), which is part of the Ministry of Finance, then reviews the dossier and the CEPP rating, and determines a reimbursement price.

competitiveness in the field of medical technology and they strongly underscore the importance of ongoing efforts of the U.S. government to open the Japanese market further to cost-saving and life-enhancing medical technologies.

Although significant progress has been made in recent decades in opening up the Japanese markets, in early 2002, however, the Japanese Ministry of Health and Welfare (MHLW) took steps that constituted a significant setback by adopting a new pricing policy that includes 'foreign average pricing' (FAP). Effective April 1, 2002, the new policy allows MHLW to cut reimbursements for medical devices based on the prices of the "similar" medical technologies in the United States and three European markets: France, the United Kingdom and Germany.²

U.S. industry has strongly opposed the basic concept of FAP and, when FAP is applied, has strongly opposed the inclusion of European prices in the Japanese FAP calculation, because many of those prices reflect artificial market-specific price controls. Accordingly, industry has reluctantly provided U.S. list prices as the only logical comparators, even though such comparisons ignore the substantial differences in the costs of doing business in the U.S. and Japan.

The MHLW FAP policy provides for existing product prices in Japan to be reduced to a maximum level of 1.5 times the simple average of the market prices observed in the surveyed countries. The 1.5 price limit is applied regardless of the actual higher costs of doing business in Japan and has not to date reflected any differences in product volumes or product types.

Japan is among the most expensive markets in the world to sell medical technology products because of a highly fragmented healthcare system. In comparison to the U.S., which has 5,800 hospitals, the Japanese sustain 9,000 hospitals, for a population that is less than half as large. Because many device products require special handling and just-in-time delivery, as well on-site clinical support and training, the actual costs of doing business can far exceed the 1.5 times limit.

In the first round of Japan FAP cuts implemented in 2002, three product groups were reduced, by up to 25% over a three year span. In its biennial pricing cuts of medical technology that will be completed in April 2004, Japan has again applied FAP cuts to several additional sectors – including two of the same product groups that were previously cut in 2002. Industry does note, however, that some progress has been gained in positive improvements to the process and dialogue related to FAP cuts – process changes which industry would like to include in future price revision processes.

It is noteworthy that all other products that were not subject to the FAP process in 2004 were nonetheless reduced by over 5%, on average. Industry is still calculating the impact of

2. MHLW Policy dated February 13, 2002, Standards for the Calculation of Insurance Reimbursement Prices for Designated Insured Medical Materials

these cuts together, but they easily amount to hundreds of millions of dollars in lost export revenue.

The Critical Role of the U.S. Government

The U.S. Government and Congress have long opposed FAP schemes, which discriminate against the U.S. medical device industry and fail to recognize the significantly higher costs of doing business in Japan.

The medical technology industry has very been grateful for the strong support of key offices of the U.S. Congress, the United States Trade Representative, the U.S. Embassy in Japan and the Department of Commerce. During both the 2002 pricing negotiations when FAP was first introduced, and more recently in the 2004 discussions, offices of the key House and Senate leadership engaged in the issue and shared their concerns directly with the Japanese Embassy and key offices of the Japanese ministry. Last year, the Chairs of the Medical Technology Caucuses, Sens. Norm Coleman (R-MN) and Evan Bayh (D-IN) and Reps. Jim Ramstad (R-MN) and Anna Eshoo (D-CA), introduced a Resolution that calls on Japan to adopt pricing policies that encourage innovation for the benefit of Japanese patients and the economy and to reduce regulatory barriers that slow the approval and adoption of new medical technologies.

In addition, the US Trade Representative and Department of Commerce expressed strong concerns in several correspondences with key Japanese offices. Finally, in the most recent discussions, U.S. Ambassador Howard Baker also expressed the concerns of the Administration with the current FAP policy, and the need for a transparent, predictable and non-discriminatory pricing framework.

Through these experiences the U.S. industry has seen some willingness to negotiate on the part of the Japanese Ministry of Health, but also notes that the application of the FAP policy itself continues to expand, in some cases contrary to the MHLW's own rules. In the 2004 discussions, for example, one product group was subject to a second FAP cut, despite rules in 2002 that would have exempted it because it had been reduced by more than 15% over the prior two pricing revisions.

U.S. industry continues to depend on support and engagement of key offices of the U.S. government in order to help curb the application of the FAP policy and to help codify favorable transparent process steps and to push for improved processes for introducing the new products we bring to Japan. Upcoming opportunities for further dialogue to bolster industry concerns include the U.S.-Japan Partnership for Economic Growth and the Enhanced Initiative on Deregulation and Competition Policy (a successor to the MOSS talks).

FAP Issues in Other Asian Countries

Since the introduction of Japan's FAP policy, other new reference policies have been introduced in Korea, and Taiwan, in both cases intended to gauge and artificially impose lower market prices. China also has seen the introduction of regional reference pricing schemes.

Korea uses unfair pricing methods based on reference prices in other countries which serve as an arbitrary cap that do not adequately reflect the market costs of doing business in Korea. In early 2003, Korea implemented price cuts of 15-40% on orthopedic and spinal products. These cuts exemplify the lack of consistency and transparency in Korean pricing determinations. Korea also discriminates against foreign manufacturers, whose reimbursement levels are capped based on documented FOB prices (submitted as part of the customs process), while the reimbursement levels for domestic manufacturers are negotiated based on self-generated and often undocumented manufacturing cost data.

In Taiwan, health authorities have begun implementing foreign reference pricing on medical devices and has requested pricing data from six countries: U.S., Canada, Singapore, Japan, Australia and France. Industry continues to be concerned about this development, which will arbitrarily cap prices on medical devices. Moreover, the National Health Insurance has unclear and non-transparent mechanisms for determining the reimbursement price of some medical products, such as coronary stents, with no clear guidelines for setting reimbursement rates.

While China has not introduced a foreign reference pricing scheme, one of its largest provinces, Shanghai, introduced an internal China reference pricing policy designed to identify and impose the lowest market price available in that market. This policy overtly discriminates against foreign firms, as it imposes a different formula for higher-end, high technology products than are applied to domestic products. While U.S. firms with the assistance of the local American Chamber of Commerce and U.S. Government were able to negotiate a mutually agreeable alternative, the situation requires ongoing vigilance to ensure that Shanghai does not implement this policy in the way originally contemplated.

Conclusion

Price controls and foreign reference pricing schemes present a unique type of challenge to the American manufacturing sectors that can still successfully compete in export markets. They undermine the local basis to establish prices and competition according to the conditions of sale and use of the products – in other words artificially imposing a “best price” from other markets in the world. The long term effect of this trend is to create incentives to drive prices up, globally, to the level of the most expensive markets in the world. Although the U.S. is the worlds largest single market and the location of the bulk of medical technology innovation, it relies on free market principles and competition to help drive down prices for domestic use. Other countries that refuse to rely on market forces essentially challenge this proposition for all other markets in the world – and seek to “freeload” on the investments in research made by other countries.

AdvaMed appreciates the shared commitment by the President and the Congress to expand international trade opportunities and encourage global trade liberalization. We look to the President and his Administration to aggressively combat barriers to trade throughout the globe, especially in Japan. AdvaMed is fully prepared to work with the President, USTR Ambassador Zoellick, the Department of Commerce, and the Congress to monitor, enforce and

advance multilateral, regional and bilateral trade agreements, particularly with our key trading partners.



Statement of Families USA

Written Testimony for the Senate Finance Committee

Hearing on International Trade and Pharmaceuticals

April 27, 2004

Mr. Chairman, Members of the Committee:

On behalf of Families USA, we are pleased to submit the following written statement on the Committee's important hearing on the issue of international trade and pharmaceuticals.

Families USA is a not-for-profit consumer advocacy organization dedicated to the achievement of high-quality, affordable health care for all Americans. This has led us to work extensively on issues related to drug pricing, because without access to affordable prescription drugs, it cannot be said that individuals have access to the health care they need.

Our testimony speaks to Americans' struggle with high drug prices and the relief that importation might offer. We believe that the important technical issues of how to ensure safe trade in pharmaceuticals can be addressed, just as they have been addressed in food, chemical, aviation and other trade areas.

The Committee is well aware of the fact that, in this country, spending on prescription drugs is rising faster than any other component of health care costs. Drug price increases are responsible for a large part—over a third—of the increase in spending on pharmaceuticals. In 2002, prices for the drugs most frequently prescribed to seniors rose nearly 3-and-one-half times the rate of inflation. Drug prices in the United States are substantially higher than prices paid by citizens of other Western industrialized nations. The high drug prices that Americans shoulder, either directly or indirectly, are to a large extent the result of policies that favor the interests of the drug industry over the interest of citizens.

Unfortunately, the recently passed Medicare Prescription Drug, Improvement and Modernization Act of 2003, continues that trend. It does little to provide real price relief for Americans. The law expressly prohibits the government from negotiating for lower drug prices on behalf of Medicare beneficiaries, as it does now for the Department of Veterans Affairs. Negotiations will be left to the regional private drug plans delivering the benefit, plans that will not have Medicare's consolidated purchasing clout. As a result, costs to Medicare will increase year-over-year and by amounts greater than they would if Medicare could negotiate prices. The law ties changes in beneficiaries' out-of-pocket exposure to Medicare's costs, so as Medicare's costs increase, so will seniors'.

Within the existing Medicare program which spends about \$8 billion a year on certain prescription drugs, the new law prevents CMS from considering therapeutic equivalence, thus blocking an important cost

containment tool. The changes in Title XI of the new law designed to speed the entry of generic drugs to market provide a little help, but the CBO says those provisions will save only \$0.6 billion over the same 10 years that the Title I pharmaceutical benefit will cost \$409.8 billion. Finally, but not least, the law (section 1121) blocks importation of cheaper drugs from Canada until the Secretary has certified that they are absolutely safe—a certification the past Administration and this Administration have both said they would not make.

Because we do so little to moderate prescription drug prices, the Congressional Budget Office estimates 8.57 percent annual inflation in Medicare's drug costs under the new law. Families USA has calculated that the senior with average drug expenses as projected by CBO, who is living at the median income, will see a share of their *total* income consumed by prescription drug expenses rise from 8.8 percent in 2006 to 12.3 percent by 2013. The 2004 Report of the Trustees of the Medicare program notes that in 2010, the combined cost of the Part B and Part D prescription drug premiums, co-pays, and deductibles will consume a shocking 36 percent of the average *Social Security* benefit; this compares to last year's Trustees' Report which shows that the Part B only premiums, deductibles, and co-payments would consume 16.6 percent of the average Social Security check. These figures show that despite the new law and an expenditure of about half a trillion dollars of national treasure, seniors and people with disabilities—particularly the near poor beneficiaries who do not qualify for extra help—will be falling behind and will be increasingly unable to pay for the prescriptions they need.

The new law is destined to fail if we cannot find a way to moderate this unacceptable rate of inflation. The 'doughnut hole' in the new drug benefit, costs entirely borne by the individual, grows from \$2,850 in 2006 to \$5,066 by 2013. A benefit leaving seniors exposed for such a large amount of their drug costs is politically unsustainable—and the sooner we address this problem, the sooner public trust in the new law will be possible.

Drug importation, particularly if limited only to Canada, is not a long-term solution to the problem of rising drug prices. It is not a substitute for the government negotiating prices. It is, however, a step toward injecting real price competition and some price transparency into the pharmaceutical market. Drug prices in Canada, as in other countries, are much more public than in the United States, where the actual prices paid by most purchasers are shrouded in mystery. This competition would put price pressures on the industry; that would result in some relief for Americans who are saddled with the highest drug prices in the world. Importation would help many to better afford the medications they need, particularly the over 43 million Americans with no health insurance who have no one to bargain for lower drug prices on their behalf. When examining importation, the Committee should keep the needs of these individuals in mind.

Much has been said about safety issues related to importation, and I am not here to negate those issues. There are safety issues with importation just as there are safety issues for sales within the US now, issues that have recently led to stepped safety requirements for drug wholesalers. As Americans continue to struggle with exorbitant and ever rising drug prices, counterfeiting that preys on low-, and even middle-income, Americans who have to choose between medicines and food will only increase. Until we have a system that makes medications affordable, counterfeiting will be a problem, with or without importation.

We manage right now to safely sell in the United States drugs made in other countries, such as Ireland and Germany; it is just that they are imported through the manufacturer and priced for US sale. We also manage to safely import a vast range of items such as vitamins, beverages, food products, chemicals, airplanes, etc that are manufactured in other countries. If these products were tampered with, there could be disastrous public health and public safety consequences. While there are concerns specific to prescription drugs, the

technology is there to ensure safety through such things as bar coding and tamper proof packaging. We are certain that the Congress can arrive at ways to adequately, and cost effectively, address safety concerns so that Americans can finally have access to drugs at prices on a par with those enjoyed by the rest of the industrialized world.

Families USA supports opening up importation to the pharmaceutical products of all advanced industrialized nations that have FDA recognized quality controls and manufacturing standards. Basically, these would be the core OECD nations. If importation is limited just to Canada, it will help individuals, but because of the ability of the huge pharmaceutical companies to control the price and quantity of product in a nation smaller in population than California, importation limited to Canadian will not be very useful in slowing the rate of prescription drug inflation in the United States. However, broader importation would bring us a de facto kind of parallel or reference pricing system that has worked well in so many other nations.

In addition, it is important to ensure that changes in the law are worded so as to allow Medicare Prescription Drug Plans and Medicare Advantage plans to buy in bulk and obtain billions and billions of dollars of savings for taxpayers and Medicare beneficiaries. Some of the new bills that have been introduced recently apply to individuals and 'wholesalers.' Any change in law should make it clear that a health plan or a State or local government seeking to obtain lower cost medicines can negotiate directly with a foreign supplier. The new law should not unnecessarily impose a new middleman step. If health plans and other large buyers can import directly, many of the safety, counterfeiting, and adulteration concerns will be moot—and the problem of millions of small packages of individual prescriptions swamping Customs and the FDA will be avoided.

Of course, importation should be regulated to ensure safety. In addition to reviewing manufacturing standards of other countries, we urge the Congress to review the safety practices of countries that engage in parallel trade in pharmaceuticals. We are, again, confident that the Congress can arrive at a feasible and cost-effective way to allow importation and finally bring some prescription drug price relief to Americans.

Having said all this, Families USA would like to make it clear that we believe the real answer is an American "home-grown" solution to the high price of pharmaceuticals. By urging importation and re-importation we are really urging the importation of other nations' political will to provide quality prescription drugs at reasonable prices. Families USA believes we should have our own political courage—our own political backbone—to do what is right for American citizens.

There is, after all, something strange in a policy that encourages larger trade deficits at a time when we are running about half a trillion dollars a year in deficits. There is something Rube Goldberg-ish in seeking to encourage the export of U.S.-made pharmaceuticals to another country, where they are opened, re-packaged, and shipped back. We know the Congress is smart enough to design a rational American prescription drug policy that finally serves the American public.

The industry will say that any reduction in its income will result in an end to research and medical advances. There are many responses to these claims—and it is important to address them. We urge the Committee to study (or ask groups like the GAO, the IOM, CRS, etc.) how certain foreign nations obtain good prices for their citizens and to identify methods by which those nations purchase drugs in a way to encourage new, truly breakthrough research and the use of effective drugs.

In spite of industry claims, we believe that, given the long-standing, extraordinary profits of the pharmaceutical industry, that it does not do enough research and development. On average, the industry's profits are much higher than its R&D. It spends too much on marketing and on the development of me-too and copycat drugs. Every prime time TV ad for a me-too, cosmetic drug is a dollar taken away from research and development of true breakthrough products. It is a shame that the industry spends almost twice as much on marketing and advertising as it spends on research. And of course, the industry spends way too much on lobbying, phony consumer front groups, and political contributions.

The enormous purchasing power of Medicare and Medicaid could and should be turned into a powerful tool to speed the development of new and breakthrough products, while paying less and less for old product and less effective products. We urge you to hold a separate hearing on ideas of how to use the purchasing power of Medicare/Medicaid/VA to obtain better prices for all Americans.

We also urge the Committee to reject the industry's pleas to raise the rest of the world's pharmaceutical prices. Such proposals give no guarantee of lower domestic prices or more effective research and development. Rightly or wrongly, American popularity abroad is at an all time low. Many of our friends question our foreign policy and our stand on world environmental issues. To now tell the consumers of the rest of the industrialized world that we want them to pay more for medicines seems very unwise, to say the least.

Finally, the Senate Finance Committee is the key to finding a way to fund research on outcomes of health care items and services. One of the most promising provisions in MMA is section 1013, which authorized \$50 million for FY 2004 and 'such sums as necessary' thereafter for medical effectiveness research. This section has the potential for enormous long-run savings by scientifically proving whether new drugs and medical devices are truly effective and worth paying more for. Time after time, we have found that new and very expensive products offered little or no new value. The only way we can slow the rate of medical inflation is to understand better what works and what doesn't. The very recent reports—many from foreign experts—about the relative danger and ineffectiveness of anti-depressants among teenagers, is just one example.

Unfortunately, \$50 million is a woefully inadequate figure for this program. And even more unfortunately, it was not funded in the President's budget. We need to devote much more to this medical effectiveness research. The budget situation facing the United States over the next decade will make it nearly impossible for the Appropriators to fund this program. Therefore, we urge Senate Finance to find a reliable funding mechanism that will grow over time. A fraction of a percent fee on the sale (including the importation) of medical devices and drugs, dedicated to the type of research described in section 1013 will save hundreds of billions of dollars in the years to come and help slow today's unsustainable rates of medical inflation.

In addition to effectively funding U.S. research on these comparative effectiveness issues, other nations are already doing a fair amount in this area, and we encourage the Committee to urge an international program of cooperative medical effectiveness research. Each nation should not have to separately and expensively repeat other nations' studies.

Thank you, members of the Committee, for the opportunity to submit this statement on behalf of Families USA.



**Comments to the Joint Hearing of the Senate Finance Committee Subcommittee on
International Trade and Subcommittee on Health Care
Submitted by Kathleen Jaeger, President and CEO**

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The Generic Pharmaceutical Association (GPhA) appreciates the opportunity to comment on international pharmaceutical trade issues before the Subcommittee on International Trade of the Senate Finance Committee. GPhA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Our products are used to fill more than one billion prescriptions every year. No other industry has made, nor continues to make, a greater contribution to affordable health care in this country than the generic pharmaceutical industry.

GPhA will set forth comments on two issues that are directly connected to international pharmaceutical trade: 1) Prescription Drug Importation, and 2) Trade Agreements.

I. Prescription Drug Importation

A. Introduction

In 1984, when the Hatch-Waxman Amendments became law, America faced a health care cost crisis similar to the one it faces today. Since that time, the generic pharmaceutical industry has matured and has provided billions of dollars in savings each year, while improving the health of millions of Americans.

GPhA shares the public's concerns about access to affordable medicine, but we also know that any long-term solution to high costs must not sacrifice safety or quality of our medicines. These are assurances that can only be offered through the strict approval process and regulation of the U.S. Food and Drug Administration (FDA).

B. Consumer Safety Must Be Paramount

Today, FDA-approved generics account for more than 51% of all prescriptions filled in the United States. Yet, generics represent less than eight cents of every dollar consumers spend on prescription drugs. These savings are in no small part the result of our Nation's commitment to free market principles. Indeed, our free market principles have been the major force in creating today's robust and competitive U.S. generic pharmaceutical industry. However, importation without adequate safeguards could shred the fabric of FDA's safety net that has protected consumers from the entry of unregulated drugs of questionable safety, potency and quality for more than 70 years.

Our industry's success, and the resulting consumer savings, stand in stark contrast to the economic experiences of other countries, such as Germany, France and Italy, which undermine pharmaceutical competition by government regulation and, hence, competitive pricing. If we permit the unregulated importation of prescription drugs, we will in effect, abandon the free market principles that have been so instrumental in allowing the generic industry to provide cost-effective prescription drugs. In turn, this could disrupt this Nation's balance between innovation and access in the prescription drug arena. In

addition, unregulated importation could undermine the 180-day generic drug exclusivity period that provides the critical incentive for generic companies to challenge invalid patents and bring affordable medicines to the market years ahead of the expiration date of the invalid patent.

Today, the quality of America's prescription medicines is by far the highest in the world. Importation of unregulated drug products could significantly undermine this quality standard that we have worked so hard to achieve. For instance, the Canadian regulatory system exempts from its health and safety standards, drugs manufactured for "export only." As a result, there can be no assurance of the actual origin of the drugs that are imported from Canada unless there is FDA supervision.

Also, there is no current system to determine whether unregulated imported drugs meet basic quality standards, or whether they have long since passed their expiration date, or are sub-potent, improperly labeled, contaminated or counterfeit. Nor are there adequate enforcement tools to stop importers of identified adulterated, misbranded or counterfeit products from re-attempting entry into the United States. Simply put, unless and until FDA has sufficient oversight over all drug importations, this Nation's drug supply chain is vulnerable to an influx of inferior and/or potentially dangerous medicines. Adequate patient safeguards therefore must first be in place to assure that unregulated imported products meet all applicable U.S. standards as a prerequisite of importation. *Otherwise, inferior and potentially lethal products may be sold unknowingly to American consumers at local pharmacies, and manufacturers of FDA-regulated imported products may be discriminated against in the U.S. marketplace.*

In testimony before the HHS Task Force on Drug Importation recently, several panelists reviewed the severity of the prescription drug counterfeit issue facing multinational brand manufacturers. Counterfeiting is not a problem found only in developing countries; it has become a growing problem all over the world. Counterfeit prescription drugs have been repackaged and reformulated in foreign countries and then introduced into legitimate distribution channels. Counterfeiting activities are well-orchestrated business enterprises, with the intention of diverting products for *robust* markets, such as the U.S. and Australia.¹ Given the gravity and breadth of the worldwide counterfeiting epidemic that plagues the pharmaceutical industry even under the current system, adequate safeguards must remain intact.

Another critical issue for consideration is whether the FDA will have the requisite resources to oversee a comprehensive import program. Without adequate resources and the time to train the requisite number of specialists to oversee such a critical program, the agency will be hard pressed to implement the necessary safeguards, provide the requisite oversight, and take appropriate enforcement actions to ensure that this Nation's drug supply system remains secure.

¹ John Theriault, Testimony before the HHS Task Force on Drug Importation, April 5, 2004.

C. Cost Savings Is Questionable

Given the necessity of developing a costly regulatory program to govern importation to ensure consumer safety as well as distribution and liability costs, the purported cost savings of importation may never be realized. Importation ignores the potential costs associated with medical treatment for consumers who have obtained poor quality drugs that don't work. It ignores the costs associated with treating consumers of unregulated drugs that are contaminated or contain harmful ingredients. It ignores the cost of treating consumers taking unregulated imported drugs that are improperly labeled. The costs of restoring America's healthcare system after importation opens the floodgate to questionable medicines must be calculated and seriously considered before any action is taken.

In addition, with importation, consumers unknowingly may end up paying more than they would if they bought an equivalent FDA-approved generic pharmaceutical here in the United States. In fact, several reports suggest that, on average, U.S. generic drugs are more affordable than Canadian generics.² Given the additional costs of unregulated importation, an assessment of the scope of potential products for importation seems prudent. Such an assessment would provide a means of ensuring consumer cost savings. Indeed, it seems counterintuitive to permit importation of unregulated imports if there is a less expensive generic already available to consumers here at home. At a minimum, unregulated prescription drug importers should be required to establish that the proposed imported product has no lower cost generic equivalent approved in the United States. Moreover, cost savings from importation should be required to be passed along to the consumer. Without this additional requirement, commercial entities could take much of the difference in prices for themselves, leaving little or no cost savings for the U.S. consumer, all the while increasing risk, adding additional costs to the government, and potentially enhancing manufacturer liability.

More importantly, unregulated importation will destroy the 180-day generic exclusivity incentive, causing our healthcare system to forfeit substantial future cost savings. This critical healthcare provision plays a significant cost containment role because it provides generic manufacturers with an incentive to challenge questionable and invalid patents. The 180-day provision has been instrumental in bringing consumers affordable medicines in an accelerated fashion, while saving billions of dollars in pharmaceutical costs. For example, 11 successful generic challenges provided over \$27 billion in savings.

D. Immediate and Available Solutions for Lowering Prescription Drug Costs

GPhA believes that the solution to high prescription drug costs will not be found in unregulated foreign imports but rather with greater utilization of FDA-approved

² Palmer D'Angelo Consulting Inc. Report Series, "Generic Drug Prices: A Canada-US Comparison," August 2002

John R. Graham and Beverly A. Robson, The Fraser Institute, "Prescription Drug Prices in Canada and the United States – Part I: A Comparative Survey," Public Policy Sources, No. 42 (2000) pp. 3-5

generic prescriptions. Generic pharmaceuticals are a safe, reliable solution to the problem of increased costs of prescription drugs. While a limited program of importing drugs from selected countries would potentially lower some drug costs for those without prescription drug coverage, increasing access to generic drugs would benefit all consumers, businesses, and government purchasers, through lower out-of-pocket and insurance costs.

There are tools available that help immediately increase generic drug utilization and savings: (1) educating consumers, physicians and states about the generic availability; (2) encouraging generic substitution; (3) employing benefit designs that incentivize the use of generics; and (4) ensuring their timely market entry.

Every 1% increase in generic utilization will result in nearly a 1% increase in savings for prescription drug payers. GPhA believes one answer to lowering prescription drug costs will be found in removing obstacles to improve access to generic medicines that already have FDA scrutiny, and already save consumers more than \$10 billion each year.

E. Prescription Drug Importation Summary

Without FDA oversight of unregulated drug importation, which at best will be expensive to implement and difficult to ensure, the U.S. drug supply chain would be particularly vulnerable to abuse. The result of importation could be an influx of adulterated, misbranded, unapproved or counterfeit medicines into this Nation's drug supply chain. While it is understandable that consumers facing high costs for prescription drugs are seeking relief, sacrificing safety for affordability is shortsighted, dangerous and unnecessary.

As Congress and state governments consider legislation and proposals to allow importation of unregulated drugs, GPhA strongly encourages these parties to look for immediate solutions in increased usage of generic medicines. We also encourage individuals to be smart consumers, and take advantage of the immediate cost savings on safe and effective, FDA-approved generic medicines.

II. Trade Agreements

Introduction

GPhA is committed to a balance between innovation and access. To that end, we also are committed to innovation in medicines and the preservation of intellectual property protections both in the United States and abroad. With balance our main concern, we believe it is essential that new trade agreements maintain parity between existing U.S. standards and requirements and those included in new trade agreements.

The generic pharmaceutical sector is uniquely impacted by the harmonization of agreements on intellectual property protections for pharmaceuticals — particularly insofar as they increase market exclusivity periods or remove necessary access provisions (e.g., the Declaratory Judgment actions). New trade agreements thus could potentially affect American consumers' access to affordable drugs as well as the business interests of the U.S. generic pharmaceutical industry. The important role that generic drugs play in providing American consumers with affordable medicines can be expanded into other nations, but only if parity exists to maintain the integrity of U.S. standards and requirements.

Unfortunately, recent trade negotiations have failed to put the interests of American consumers first. For example, in the just-concluded U.S.–Australia Free Trade agreement, fails to require the Bolar provision — which ensures that generic medicines enter the market immediately after patent expiry to improve access and encourage competition. The U.S.-Australia FTA also provides for market exclusivity that extends slightly beyond the U.S. provisions of 5 years of market exclusivity for new chemical moieties and 3 years of market exclusivity for new products. (See Article 17.10 (1) (c)) “at least five years”). At a minimum, GPhA believes that the concept of 5 year market exclusivity within trade agreements be accompanied by the Bolar Provision, without accruing any additional market exclusivity or patent extension benefits. Moreover, if linkage between patents and product approvals is to be embraced, that it be done in the context of the entire construct of U.S. law, including recent statutory changes enacted in Title VII of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. GPhA accordingly supports a balanced trade approach. One that includes the following key access issues:

1. Market Exclusivity

U.S. law establishes that a generic applicant cannot submit an abbreviated new drug application for a product that contains the same active moiety as in the new chemical entity for a period of 5 years from the date of the approval of the first approved new drug application. Art. 39.3 of TRIPS establishes that “Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products, which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves considerable effort, shall protect such data against unfair commercial use.” However, it does not establish any specific period for such market exclusivity.

Access to such data is necessary for generic companies to be able to submit early applications for the marketing approval of much needed generic drugs. Market exclusivity extensions could result in unnecessary delays of the application for marketing approval of generic companies. Such delays result in increased pharmaceutical costs for consumers.

GPhA strongly opposes any extension to market exclusivity concepts beyond what it is currently in the U.S. law. Last November, we also expressed our

opposition to the language that was proposed in the draft of the Free Trade Area of the Americas (FTAA) (Section 10. Article [1.2], [1.4], to establish “at least” five years of data protection). We have seen with great concern that the text of the FTA that was recently concluded with Australia states “at least 5 years.” GPhA strongly opposes inclusion of similar language for all future agreements as such language can potentially delay consumer access to more affordable medicines both in the United States as well as in its trading partners. It is essential that consumers have access to affordable drugs immediately after the expiration of a patent.

2. Bolar Provision

The “Bolar” provision is a critical U.S. provision that allows for the development, testing and experimental work required for the registration of a generic medicine during the patent period of the original product. The purpose of this provision is to ensure that generic medicines enter the market immediately after patent expiry to improve access and encourage competition. This provision has been upheld by the World Trade Organization (WTO) as conforming to the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) in a WTO dispute ruling. In its report adopted on April 7, 2000, a WTO dispute settlement panel said Canadian law conforms to the TRIPS Agreement in allowing manufacturers to develop the necessary registration information and test data. (The case was titled “Canada — Patent Protection for Pharmaceutical Products”).

Recent FTAs do not specifically state that that the Bolar Provision should be included in the legislation or regulations of the Parties. Clearly, the omission of the Bolar Provision is of grave concern to GPhA. This provision is essential to ensure that consumers have access to more affordable drugs as soon as a patent expires and has proven to be an effective measure in the United States that could also be of benefit to other nations. We believe that it is essential that future trade agreements include specific language to ensure its inclusion in the laws of the Parties.

3. Linkage

U.S. regulations establish an intellectual property-based abbreviated approval process. Simply put, it includes a linkage between certain types of patents and abbreviated product approvals. The end result is that the U.S. government is precluded from approving a generic pharmaceutical if certain patents are deemed valid and infringed by the generic product. Linkage in the United States was intended to promote pharmaceutical innovation while at the same time allowing access to affordable medicines.

However, linkage has, in some cases, led to unnecessary delays in generic competition stemming from patents improperly listed with the U.S. government. GPhA is concerned that the U.S. government may be requesting other countries to

include an “automatic” linkage, despite no such parallel system components in current U.S. law. For example, under the U.S. approval system, the linkage is not automatic. A possible delay by the FDA in its analysis and approval of a generic drug due to an existing patent only occurs after the patent owner brings suit for patent infringement within 45 days of receipt by the patent owner of the notice of certification of the ANDA at the FDA. Failure of the patent owner to act within that time frame allows the FDA to proceed with the approval process of the drug (Title 21, Chapter 1, Part 314.107(b)(3)). Moreover, only certain types of patents are subject to that linkage.

GPhA opposes the inclusion of automatic linkage in trade agreements as we believe that it has resulted in unnecessary delays to the entry of generic drugs into the market. In addition, GPhA believes that if the concept of linkage is adopted in trade agreements, it must be done in the context of the entire construct of U.S. law, including recent statutory changes enacted in Title VII of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. These changes include among other things: (1) the elimination of multiple 30-month stays of FDA approval of a generic drug application with a paragraph IV certification while the courts determine whether the patent has been infringed; and (2) permit a generic applicant to pursue a court challenge to the listing of a patent in the Orange Book under a declaratory judgment concept.

Conclusion

As the trade association representing a major industry in a key industrial sector, GPhA supports efforts to negotiate trade agreements with other nations. We believe that such agreements can be beneficial both to global consumers and our member companies if their content reflects parity with established U.S. laws, standards and regulations governing the marketing of generic pharmaceuticals. Without such parity, American consumers — who have come to depend on affordable generic medicines to help them lead longer, healthier and more productive lives — are at risk of delayed access to the substantial savings created by generic competition.

**Testimony of the Pharmaceutical Research and Manufacturers of America
(PhRMA)**

**Hearing before the Subcommittee on International Trade and Subcommittee on
Health Care of the Senate Finance Committee**

Hearing on International Trade and Pharmaceuticals

April 27, 2004

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to present this testimony for the record on the important issue of foreign government price controls on pharmaceuticals. These government measures, prevalent in many of our country's major trading partners such as the European Union countries and Canada, impose major costs on those economies as well as on that of the United States. Most importantly, price controls in these countries hurt patients both here and abroad. Obtaining market-based reforms is one of the highest global priorities for our industry, and PhRMA strongly support the tremendous importance of elevating this issue on the U.S. trade policy agenda.

Background on Foreign Pharmaceutical Market Access Barriers and Price Controls

Most governments outside the United States offer some kind of national health insurance that covers the vast majority of the population. As a result, such governments dominate the health care "marketplace," and effectively operate as monopsonistic purchasers of pharmaceutical products. Due to the long history of government intervention and support in these countries, doctors generally will not prescribe and patients will not purchase medicines that are not approved for reimbursement under the government health plan. For most drugs, the private market in these countries does not exist. Many governments abuse this near-total control of the local health care market (backed up by their legal authority to compulsory license our products) to obtain drugs at below-market prices and avoid paying for the research and development costs of discovering and developing them.

Foreign government intervention in the pharmaceutical market takes a wide variety of forms. Although referred to in this testimony as "foreign price controls" for simplicity's sake, that term is intended to encompass the wide variety of mechanisms that most governments outside the United States employ to restrict the supply of pharmaceuticals to artificially low levels or to depress patient and doctor demand for the latest products. Some countries rely on government-set ceiling prices, while others demand regular, large "rebates" from pharmaceutical manufacturers. Still others use profit controls, volume restrictions, or highly-restrictive formularies. Some countries

even fine doctors if they prescribe “too many” innovative medicines for their patients in a given month. All of these mechanisms distort market-based trade.

Moreover, the negative ramifications of price controls are not confined to the market in which they are imposed. There are two major mechanisms through which stringent price controls in one country distort trade in other OECD markets. The first mechanism is the practice of many countries of setting prices based on the lowest price, or the average price, in certain other countries. These reference countries invariably impose their own forms of price controls, the effects of which are then magnified internationally through the reference pricing mechanism.

The second mechanism that magnifies the international effect of price controls is parallel trade. This is a particular problem in Europe. Unlike normal trade flows that occur because of differences in competitiveness and encourage economic efficiency, parallel trade in pharmaceuticals in Europe occurs primarily because of differences in national regulatory regimes and the different prices that result from different bureaucratic formula that government officials impose to control pharmaceutical prices. Parallel trade thus magnifies the impact of the most stringent government price control regimes and results in distortions even in markets in which the government takes a less interventionist stance.

Foreign Market Access Barriers and Price Controls Discriminate Against Innovative Products and Depress Innovation

These practices systematically discriminate against innovative pharmaceutical products. Generally the discrimination operates by (a) delaying the introduction of new, innovative medicines, and (b) systematically limiting the prices and volumes for new innovative medicines below levels that would be set by a competitive marketplace. At the same time, locally produced generic prices are kept artificially high – significantly higher, on average, than in the U.S. For example, many countries around the world practice a form of reference pricing pursuant to which the price of a new drug is tied, by law, to the price of older and typically less effective off-patent medicines. By design, these systems are set up to compensate innovative products at the same rate as generic products, and undermine the value of pharmaceutical patents in that market.

These systems almost completely ignore the massive investment of R&D necessary to invent and develop a new medicine. Today, the process of bringing a drug to market takes up to 15 years. As a result, the average cost to develop a new drug has grown from \$138 million in 1975 to over \$800 million. The risks involved in the new drug development and approval processes are also substantial. Of every 250 drugs that enter preclinical testing, only 1 is approved by the FDA. Only 3 out of 10 marketed drugs produce revenues that match or exceed average R&D costs. Yet a growing number of countries around the world nevertheless establish prices for innovative new drugs at exactly the same level as the price of older off-patent medicines.

The discrimination against new innovative pharmaceuticals depresses the incentives for future innovation that would occur in the absence of such government price controls. By reducing the level of pharmaceutical research, government price controls reduce the number of new medicines that are discovered. Patients in the U.S. and around the world are denied treatments for conditions and diseases for which no adequate or effective therapy currently exist. Patients are also denied the benefits of medicines that, while similar to existing medicines, may have fewer side effects. One recent study estimates that if price controls had been in place between 1980 and 2001 in the United States, between 330 and 365 new medicines would not exist today.¹

Foreign Market Access Barriers and Price Controls are Bad for Patients

These mechanisms are bad for patients. As nearly all would agree, new medications are a critical element of quality health care. Yet many patients in countries that employ price controls often wait years before gaining access to breakthrough drugs. In the majority of foreign countries, a marketing authorization alone is not sufficient to enable a prescription drug to actually be sold. The medicine will appear on the market only after government bureaucrats have fixed a price and/or the medicine has been registered on the positive list defining the conditions under which it is covered by the national health insurance scheme.

Governments often delay adding new products to national reimbursement lists merely to avoid the cost of providing those treatment options to patients. In China, for example, no products introduced after 1998 have been added to government reimbursement lists. The same startling fact is true in Poland; the government has not approved a single new product for inclusion on the national reimbursement list since 1998. Other countries are also problematic in this regard – the government price control bureaucracy in several western European countries routinely delays market entry for new products by over one year.² In Austria, Finland, France, Greece and Portugal, for example, it takes on average between 332 and 404 days to get an *approved* new drug on the government reimbursement lists. It is no wonder then that a February 2003 report in *Business Week* stated that, “As a result of price controls, European consumers are heading toward second-class citizenship when it comes to access to medicine.”³

Similarly, a study that examined regulatory delays in Canada, entitled, *Prescription Drug Costs: Has Canada Found the Answer?*, found that one way Canada tries to control costs is by dragging out the process of approving expensive new drugs, no matter how beneficial they are. The federal approval process takes 13 percent longer than in the United States. The study also found that, “Even if a drug wins federal approval [in Canada], it faces 10 more hurdles - the 10 provinces. Each province has a review committee that must approve the drug for its formulary. Of 99 new drugs approved by the

¹ C. Giaccotto, R. Santerre, and J. Vernon, “Explaining Pharmaceutical R&D Growth Rates at the Industry Level: New Perspectives and Insights,” AEI-Brookings Joint Center for Regulatory Studies, Publication 03-31, December 2003.

² “Delays in Market Access,” Cambridge Pharma Consultancy (a unit of IMS Health), December 2002.

³ Kerry Capell, “Europe Pays a High Price for Cheap Drugs,” *Business Week*, February 17, 2003.

federal government in 1998 and 1999, only 25 were listed on the Ontario formulary. Further, the provincial approval times vary greatly from province to province. The wait for approval in Ontario is nearly 500 days.”⁴

Even after a drug is approved, foreign government price control measures lead to less diffusion of new medicines compared to the United States. A 2002 survey entitled, “Diffusion of Medicines in Europe,” found shortfalls in the diffusion of state-of-the-art medicines between European countries for 20 key diseases. The study noted that the shortfalls in diffusion of new medicines resulted in large part from price containment measures.⁵ Specific examples of the impact of price controls on patient access follow:

- **Cardiovascular Disease** - In Germany, 87 percent of all patients with coronary heart disease were not treated with modern lipid-lowering drugs. In Italy, 83 percent of eligible patients did not receive statins.
- **Multiple Sclerosis** - In France, “less than 50 percent of patients [with Multiple Sclerosis] eligible for treatment with beta interferons actually receive it (only 10,000 from about 25,000 to 30,000).”
- **Schizophrenia** - In France it is estimated that there are 4.4 schizophrenia sufferers for every 1,000 people aged between 31 and 50 years, but only 2.4 people for every 1,000 are treated. For the treated patients the level of the use of innovative second generation drugs continues to be at a very low level.
- **Depression** - “The European average shows that only 18 percent of patients with severe depression received treatment with antidepressants.” In Germany, of the percent of patients treated with antidepressants, “only one in three received an up-to-date treatment with modern antidepressants (SSRIs). The other 8 percent are treated with older substances with more side effects or less effective drugs like herbal preparations.” In France, “recent studies have shown that 50 to 70 percent of patients with symptomatic depression are not treated at all, either with interpersonal or behavioural psychotherapies nor with antidepressant medication or a combination of both.”⁶

Not only do price control measures lead to delays in the use of new medicines, they also tend to increase the use of older medicines. A recent study by IMS Consulting examined data from the U.S. and Europe, the two largest biotech markets, over the last ten years, and found that American patients have benefited through the introduction of more biotech medicines, and these medicines have been on the market for longer periods of time. The report also noted that not only do Americans have access to a greater

⁴ William McArthur, “Prescription Drug Costs: Has Canada Found the Answer?” National Center for Policy Analysis - Brief Analysis No. 323, May 19, 2000.

⁵ O. Schöffski, “Diffusion of Medicines in Europe,” Prepared for the European Federation of Pharmaceutical Industries and Associations (EFPIA), September 2002.

⁶ *Id.*

number of biotech medicines than Europeans, they also tend to use relatively newer products.⁷

Similarly, a December 2002 report from the U.S. International Trade Commission examined pricing of prescription drugs and found that when a drug is widely available in the market the “effect of the cost-containment programs in some countries is the increased likelihood that older, lower cost products would be prescribed rather than newer, more innovative products.”⁸

Foreign Market Access Barriers and Price Controls Hurt National Economies and Can Actually Increase Health Care Costs

Given that the imposition of government price controls on innovative pharmaceuticals have such significant negative ramifications for the quality of medical care abroad, one would hope that such measures at least serve their intended purpose of saving government’s money. In fact, the opposite is true. By introducing these distortions into their national marketplace, recent evidence demonstrates that foreign governments actually incur substantial economic losses and higher costs elsewhere in their health care system.

A recent study by Bain & Company for the World Economic Forum⁹ examined the impact that price controls and other forms of cost-containment have had on Germany. The study found that although Germany spends 40% less per capita on drugs than the United States does (which saved Germany \$19 billion in 2002), the country’s related losses totaled \$22 billion, leaving it with a net loss of \$3 billion. The losses occurred in a variety of areas, including: R&D spending (\$3 billion); additional innovation spending that this R&D would have stimulated (\$900 million); in lost patent value (\$200 million); in lost high value-added jobs and the taxes not paid on them (\$4 billion); in associated jobs not created in supply and services industries (\$3.7 billion); in government training of high value-added workers (\$200 million); in lost corporate centers, corporate taxes and local startup companies not spawned by these corporate centers (\$5 billion); and in poorer health outcomes driven by lowered access to the most innovative drugs (\$5 billion).¹⁰

In addition to imposing other costs throughout the economy, foreign price controls can actually increase health care costs for the governments that use them. Recent studies and reports have confirmed what many have assumed for years – pharmaceuticals often substitute for more costly hospital and physician care. A study in the September/October 2001 issue of *Health Affairs* by Frank R. Lichtenberg of Columbia University examined the association between the use of newer medicines and

⁷ IMS Health, “U.S. Outpaces Europe in Growth of Emerging Biotech Market: Industry Prospective”, January 17, 2003.

⁸ U.S. International Trade Commission, “Pricing of Prescription Drugs,” Publication 3333, (Washington, D.C.: U.S. International Trade Commission, December 2000.)

⁹ “Addressing the Innovation Divide,” Bain & Company, Inc., Presented at the Annual Meeting, Governors of the World Economic Forum for Healthcare, January 22, 2004.

¹⁰ *Ibid.*

morbidity, mortality, and health spending. Lichtenberg found that patients using newer drugs were significantly less likely to die and lose workdays than those using older drugs. He also found that the use of newer medicines increased drug costs by \$18, but reduced hospital and other non-drug costs by \$129,¹¹ meaning that for each additional \$1 spent on newer pharmaceuticals, \$6.17 is saved in total health care spending. This is powerful evidence that new drugs not only save lives – they save money by reducing the need for other, more expensive treatments such as hospitalizations, emergency-room visits, and nursing-home care.

Foreign Market Access Barriers and Price Controls Harm U.S. Exports and Cost U.S. Jobs

Notwithstanding all of this evidence that foreign price controls hurt patients and cost national economies dearly in terms of lost R&D and increased costs in other aspects of the health care system, the superficial appeal of these cost-containment measures has proved irresistible to most of America's trading partners. U.S.-based and U.S.-operated research pharmaceutical companies lead the world in developing and manufacturing new medicines. As a result, it is easy for foreign governments to focus their cost-cutting initiatives on innovative pharmaceutical products, rather than other participants in their health care systems, such as local pharmacists, local wholesalers, or local generic drug producers.

The pharmaceutical industry is a key component of America's high tech economy. The pharmaceutical sector contributed \$229.2 billion in sales, \$75.4 billion in labor income, and nearly 1.1 million employees to the U.S. economy in 1999 alone. The average wage in the industry is over \$18 per hour. The industry is among the top U.S. exporting industries, and ranks with the semiconductor, aerospace and computer industry in the value of its exports. Foreign price controls, however, systematically depress these exports and hurt our manufacturing sector.

By impeding the ability of the pharmaceutical industry to access foreign markets in a meaningful way, foreign governments not only depress U.S. exports, but also effectively force U.S. consumers to bear an unfair portion of the cost of researching and developing new medicines. As FDA Commissioner Mark McClellan's recently remarked, "We cannot carry the lion's share of this burden for much longer." U.S. research jobs, U.S. manufacturing jobs and U.S. patients' access to new cures and therapies are all at stake.

Opposition to Foreign Market Access Barriers and Price Controls Should be a Core Element of U.S. Trade Policy

The pernicious effects of foreign price controls hurt patients, in the United States and abroad, hurt U.S. exports, cost good, high-quality U.S. jobs, and are not sound

¹¹ F. Lichtenberg, "Benefits and Costs of Newer Drugs: An Update," National Bureau of Economic Research, June 2002.

economic policy even for the countries that employ them. For all of these reasons, reform of foreign pharmaceutical markets should be a top priority of U.S. trade policy.

International agreements and U.S. legislation both provide sufficient scope for trade action directed toward foreign price and access controls for pharmaceuticals. Although no existing trade agreement imposes comprehensive disciplines on trade-distorting government price controls, the GATT has recognized the problematic nature of such government interventions since 1947. Article III:9 of that seminal trade agreement provides as follows:

“The contracting parties recognize that internal maximum price control measures, even though conforming to the other provisions of this Article, can have effects prejudicial to the interests of contracting parties supplying imported products. Accordingly, contracting parties applying such measures shall take account of the interests of exporting contracting parties with a view to avoiding to the fullest practicable extent such prejudicial effects.”

This text is evidence of countries’ recognition that price controls can prejudice the trade interests of other countries and such prejudicial effects should be avoided.

Over the past several years, the U.S. Government has also recognized the potential harm to U.S. trade interests as a result of certain countries’ practices in this area. For example, in the U.S.-Japan Enhanced De-Regulation Initiative, initiated back in 1998, Japan committed to “recognize the valuation of innovation of pharmaceuticals” and “ensure transparency in the consideration of health care policies.” *Birmingham Agreement (May 15, 1998)*. Bilateral efforts were also effective in improving the commercial environment in Korea during 1999-2001, when Korea agreed to list imported medicines on its National Reimbursement List for the first time, and abandon a reference pricing scheme that would have disproportionately undermined the pricing of innovative medicines.

PhRMA welcomes recent steps taken by the Administration to begin to grapple with this complex set of issues in a more comprehensive fashion. The U.S.-Australia FTA, concluded earlier this year, represents an important step in the right direction. While PhRMA is disappointed that not all market distortions and aspects of discrimination against innovative companies were resolved in the Agreement, we appreciate the important gains made in improving the transparency and fairness of the review process for new drugs in that country. We are pleased that the Agreement contains a strong statement of principle on the importance of innovative pharmaceuticals and pharmaceutical R&D, and look forward to those principles being given effect in Australia.

PhRMA also welcomes the recent appointment of Ralph Ives, a veteran USTR negotiator, to the position of Assistant USTR for Pharmaceutical Policy. We look forward to working with Mr. Ives and his team in advancing U.S. trade policy interests

and the interests of U.S. patients relating to foreign health care reform and global research and development.

We strongly urge the Administration to look for additional bilateral and multilateral opportunities to begin a dialogue with our trading partners that have exploited these price controls for so long. The aging world population in developed countries such as the G-8 reinforce the vital importance of continuing to foster the development of innovative new medicines. The USTR in particular should use the ample existing trade authorities granted to him by Congress to pursue this issue. Whether it is through the annual Special 301 review, or incorporating this issue into other ongoing trade policy initiatives, USTR should look for every possible opportunity to communicate the importance of this issue to our trading partners.

At the present time, the U.S. pharmaceutical industry faces major new threats from onerous price controls regimes in several major European countries. In Germany, for example, the government has recently determined to implement a new reference pricing system for patented molecules. The details of this system are still under review by the government, and U.S. trade officials should engage with their German counterparts on an urgent basis to defend the importance of maintaining a market-based pharmaceuticals sector in Germany and prevent the type of discrimination against innovation that is so prevalent in other European countries and so detrimental to U.S. trade interests.

Canada is also a major continuing concern. The Patented Medicines Price Review Board establishes a maximum legal price pursuant to which pharmaceutical products can be sold in Canada. Layered on this national level of price regulation is a complex web of provincial regulations that further distort the market and depress prices and volumes of drugs sold in that country. The province of Ontario, for example, has had a price freeze in place for almost ten years now, and routinely delays market access for new drugs in the province by over one year as its bureaucracy reviews the pricing criteria. These manipulations of local prices in turn cause economic harm to the United States and fuel the current illegal and dangerous trade in unregulated prescription drugs.

Two East European countries are also of particular concern. Poland represents the largest pharmaceuticals market in Eastern Europe and will join the EU on May 1. Yet the Polish government's intervention and distortion of the pharmaceutical marketplace is excessive even by European standards. As mentioned, the government has approved no new products for reimbursement for over five years. In addition, the government is currently threatening to impose over \$1 billion dollars worth of fines on PhRMA member companies for allegedly failing to comply strictly with the government's nebulous and ever-shifting cost control strategies. In Hungary, the government passed just this month a new price control measure effectively cutting all pharmaceutical prices by 15%. As of May 31st, this measure will give the government absolute and unbridled discretion over such prices, and was passed with almost no consultation whatsoever with stakeholders in the marketplace.

Apart from these current country-specific priorities, PhRMA notes the importance of the study mandated in the recent Medicare legislation passed last fall. Under that legislation, the U.S. Department of Commerce and the USTR, among other agencies, are responsible for studying the effects of foreign price controls in the United States and abroad. This is an important exercise and PhRMA is confident that it will demonstrate substantial harm to consumers here and abroad from interventions by foreign governments that distort international pharmaceutical markets.

Conclusion

We thank the Subcommittees for the chance to present this testimony for the record and appreciate the important work of the Subcommittee in focusing attention on this critical trade issue.